

# **EPA Jacket 2724-488**

## **Vol.1**

# Receipt for Section 3

S: 778309

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Enter More Information

Company: 2724 WELLMARK INTERNATIONAL

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 81

Product #: 2724-448 Product Name: ZOECON RF-330 ALTOSID PELLETS

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 18-Mar-2005

OPP Rec'd Date: 21-Mar-2005

Receipt Content

Front End Date: 21-Mar-2005

Risk Manager Send Date: 23-Mar-2005

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

notification.

MAR 23 2005 BPRD

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

SEP 30 2005

98-10

332  
C. Pollard

AIC  
MAR 25 2005

sdh

**Receipt for Section 3**

S:

Regulatory Type:  Resubmission: ☐ Yes ☒ No

Application Type:  Fee For Service: ☐ Yes ☒ No

Company:   ☒

Risk Manager:

Product #:  Product Name:

Override#:

Me Too Section3:  Me Too Product Name:

Application Date:  ☒ OPP Rec'd Date:  ☒

Front End Date:  ☒ Risk Manager Send Date:  ☒

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Form A: ☐ Signature Date:  Form B: ☐ Signature Date:

New Ingredient Request Date:   
New Ingredient Received Date:

**Print Letter**  
**Enter More Information**

**Receipt Content**

*BPPD  
MAY 19 2004*

AIO  
JUN 4 2004  
sdh

S: 763148

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Print Letter

Application Type: Amendment

Fed For Service: ☒ Yes ☐ No

Enter More Information

Company: 2724 WELLMARK INTERNATIONAL

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 2724-448 Product Name: ZOECON RF-330 ALTOSID PELLETS

Overide#:

Me Too Section3: Me Too Product Name:

Application Date: 30-Jun-2004

OPP Rec'd Date: 01-Jul-2004

Front End Date: 02-Jul-2004

Risk Manager Send Date: 16-Jul-2004

Receipt Content

Study

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

JUL 20 2004

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date:

Form B: Signature Date:

305 Andy - Captain  
Carole Pollard - Fexmed RAC

BLOO

ATC  
JUL 23 2004

sdh



**Receipt for Section 3**

S: 762853

Regulatory Type: Product Registration - Section 3 ☐ Yes ☒ No

Application Type: Miscellaneous Receipt ☐ Yes ☒ No

Company: 2724 WELLMARK INTERNATIONAL ☒

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 81

Product #: 2724-448 Product Name: ZOECON RF-330 ALTOSID PELLETS

Override#:

Me Too Section3:  Me Too Product Name:

Application Date: 24-Jun-2004 ☒ OPP Rec'd Date: 25-Jun-2004 ☒

Front End Date: 25-Jun-2004 ☒ Risk Manager Send Date: 29-Jun-2004 ☒

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

revised CSF per telephone conversation.

New Ingredient Request Date:

New Ingredient Received Date:

Form A ☐ Signature Date:  Form B: ☐ Signature Date:

Print Letter

Enter More Information

Receipt Content

Data has been modified, Point-Click 'Save' when Finished!

*CP*  
rec'd 7/29/04

response code: 37  
date 7/29/04

AIO  
JUL 29 2004

*sdh*

**Receipt for Section 3**

S: 743047

Regulatory Type: Product Registration - Section 3 ☐ Ret submission ☐ Yes ☒ No

Application Type: Amendment

Company: 2724 **WELLMARK INTERNATIONAL** ☒

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 2724-448 Product Name: ZOECON RF-330 ALTOSED PELLETS

Overday:

Me Too Section3:  Me Too Product Name:

Application Date: 30-Jul-2003 ☒ OPP Rec'd Date: 01-Aug-2003 ☒

Front End Date: 01-Aug-2003 ☒ Risk Manager Send Date: 01-Aug-2003 ☒

Fast Track: ☐ Studies: ☐ New Ingredient: ☐

Receipt Description:

*Updated CSF*

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:  Form B: ☐ Signature Date:

*98-10*  
*Maxi*  
*332*

*Linda,*

- RAL added in OPPIN
- ~~unable to enter action code "332"~~

*sdh*  
*8/25/03*

*response code: 38*  
*date 7/29/09*

*FTT log*  
*AUG 25 2003*  
*sdh*



**SANDOZ****FAX****Regulatory Affairs, 1300 E. Touhy Ave., Des Plaines, IL 60018****To:** Mr. Willie Nelson  
EPA / BPPD**Tel:**  
**FAX:** (703) 308-7026**From:** Steve Spaulding**Tel:** (847)-390-3007**FAX:** (847)-390-3022**Pages:** 2 (including cover page)**cc:****File:** Altosid Reregistration**Date:** February 24, 1997

If you do not receive all pages of this fax, please call (847)-390-3007 or 390-3672

**SUBJECT:** ALTOSID (Methoprene) Phase 5 Reregistration  
(EPA Reg. Nos. 2724-392, 2724-393, 2724-375, 2724-421, 2724-446,  
2724-448)

Dear Mr. Nelson:

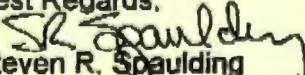
As a followup to my February 12, 1997 submission of revised labels and CSF's for 6 ALTOSID (methoprene) end-use products and our telephone conversation last week, I have attached the cover page of the agenda for the American Mosquito Control Association Meeting in Salt Lake City on March 23-27, 1997.

There is considerable interest from mosquito abatement districts attending this meeting to expand the use of ALTOSID products as a result of the recent EPA approval to remove fish habitat application restrictions from the label. This change along with the addition of a toxicity statement concerning aquatic dipteran species were added to the labels included in the February 12 submission.

We would like to provide this user group proof that these label changes have been approved by EPA, therefore I would like to request expedited review of the February 12 submission in order to be able to provide EPA-approved copies of the label to our customers at the meeting. In order to distribute new labeling at the meeting, we would need to have stamped-approved copies of the labels by March 19 at the latest.

Thanks in advance for your help and cooperation on such short notice. Please contact me at (847)390-3007 if you have any questions.

Best Regards,

  
Steven R. Spaulding  
Manager, Regulatory Affairs



*This program is provided by:*



SIXTY-THIRD  
ANNUAL MEETING  
of the

**AMERICAN  
MOSQUITO  
CONTROL  
ASSOCIATION**

*Salt Lake City  
1997*



*"This is the place. this is the time."*

MARCH 23 - 27, 1997  
LITTLE AMERICA HOTEL  
SALT LAKE CITY, UTAH

HOSTED BY THE

*Utah*  
**MOSQUITO  
ABATEMENT**





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 23 1996

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**Memorandum**

Subject: Review of Ecotoxicity Data Submitted in Compliance with the Methoprene RED  
(DP Barcode D226999, Case No. 003099, MRIDs 440221-01 and 440221-02)

From: Mark J. Perry, Biologist  
Biopesticides and Pollution Prevention Division (7501W)

Thru: J. Thomas McClintock, Team Leader  
Biopesticides and Pollution Prevention Division (7501W)

To: Willie Nelson, Regulatory Action Leader  
Biopesticides and Pollution Prevention Division (7501W)

*Handwritten notes:*  
Mark J. Perry  
10/12/16  
JTM - 10/13/16

**Action Requested**

Sandoz Agro, Inc. submitted a chronic toxicity study performed with mysid shrimp (guideline reference 72-4) and a study evaluating non-target effects in metropolitan wetland areas (non-guideline). Both studies were performed with technical methoprene and were submitted in response to the methoprene RED. The non-guideline study was required by the Agency prior to reclassification of methoprene as a biochemical. This study also evaluated the use of *B. thuringiensis israelensis* as a mosquito larvicide.

**Results/Conclusion**

The non-target effects in metropolitan wetland areas (non-guideline) study is classified supplemental; it was not conducted following GLP regulations 40 CFR 160. Although the study may provide useful information, it does not satisfy the data requirement. In general, the results of the study indicate that, with field use of methoprene in wetlands, adverse ecological effects on non-target organisms were either not present or were unmeasurable due to natural variability or study design constraints.

The chronic toxicity (72-4) study was conducted according to acceptable procedures and determined the following values for methoprene technical to mysid shrimp (*Mysidopsis bahia*): LOEC of 25  $\mu\text{g a.i./L}$ , NOEC of 14  $\mu\text{g a.i./L}$ , and MATC  $> 14$  and  $< 25 \mu\text{g a.i. l}$  (geometric mean MATC = 19  $\mu\text{g a.i./L}$ ). This study was adequately conducted (core) and provides acceptable data. Although the results are valid, the expected effect on aquatic invertebrates cannot be evaluated without the estimated environmental concentration (EEC) determined from the recommended use levels for this product.

# DATA EVALUATION REPORT

METHOPRENE

STUDY TYPE: NON-GUIDELINE STUDY

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831

Primary Reviewer:

Sylvia S. Talmage, Ph.D., D.A.B.T.

Signature: *Sylvia S. Talmage*

Date: October 2, 1996

Secondary Reviewers:

Robert H. Ross, M.S., Group Leader

Signature: *RHR*

Date: 10-3-96

Paul G. Forsyth, Ph.D.

Signature: *Paul G. Forsyth*

Date: 10-3-96

Quality Assurance:

Susan Chang, M.S.

Signature: *SSC*

Date: 10/3/96

## Disclaimer

This Data Evaluation Report may have been altered by the Biopesticides and Pollution Prevention Division subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464



**METHOPRENE**

Non-Guideline Study

EPA Reviewer: Mark J. Perry  
Biopesticides and Pollution Prevention Division  
EPA Team Leader: Roy D. Sjoblad, Ph.D.  
Biopesticides and Pollution Prevention Division

Date: 10-22-96Date: 10/23/96**DATA EVALUATION REPORT**

**MRID# & TITLE OF STUDY:** MRID 44022102, An Assessment of the Non-Target Effects of the Mosquito Larvicides, Bti and Methoprene, in Metropolitan Area Wetlands

**DB BARCODE:** D226999  
**REG./FILE#:** 002724-00375

**CASE:** 003099  
**CHEMICAL/BIOL#:** 105401 Methoprene

**COMPANY/SPONSOR:** Sandoz Agro, Inc.

**TEST MATERIAL:** Methoprene

**REVIEW CONCLUSION:** This non-guideline study is classified supplementary; it was not conducted following GLP regulations 40 CFR 160. The original data, particularly for the Wright County Long Term Experiment, should be provided in order to perform a more definitive evaluation. In general, the results of the studies indicated that, with field use of methoprene in wetlands, adverse ecological effects on non-target organisms were either not present or were unmeasurable due to natural variability or study design constraints.

**RECOMMENDATIONS:** The sponsor should provide copies of the original unpublished laboratory and field studies for review. The Wright County Long Term Experiment could serve as a Tier IV Simulated or Actual Field Testing for Aquatic Organisms (Guideline M 154A-34) if the entire report including raw data were submitted. A combination of the Wright County Long Term Experiment and the Wright County Historical Survey could serve as a Tier IV Simulated or Actual Field Testing for Birds (Subdivision M, Guideline 154A-33) if the entire report including raw data were submitted.

**ADEQUACY OF STUDY:** Supplementary; this study was not intended to fulfill a guideline requirement but was intended to support reregistration of methoprene.

**MATERIALS & METHODS:** The study summarizes five field studies in which the effects of the application of methoprene to Michigan wetlands on non-target organisms was evaluated. The individual studies were suggested and sponsored by the Scientific Peer Review Panel of the Metropolitan Mosquito Control District and addressed the long-term ecological effects of a larvicidal program. As such, these studies did not follow the principles of GLP as outlined in 40 CFR Part 160. Additional methodology is summarized under the discussion of the individual studies.

**REPORTED RESULTS:** The results were provided as summaries of the five individual studies.

1. In the Wright County Historical Survey, no statistical differences in growth, reproduction, or return rates of red-winged blackbird populations or species composition and density of invertebrates were found between wetlands treated with methoprene and untreated sites.



2. In the North Metropolitan Area Bird Survey, observed differences in bird populations between untreated wetlands and wetlands historically treated with either methoprene or another larvicide were not clearly treatment related. No distinction between methoprene-treated sites and sites treated with the other larvicide was made.
3. In the Lake Maria Study, no statistically significant changes in densities of zooplankton, insects, or benthic invertebrates were observed between the methoprene-treated and untreated areas of Lake Maria. However, densities were too low for the statistical evaluation to be rigorous.
4. In the Mallard Duckling Study, differences in duckling weight were observed after five days (first trial) between treated and untreated sides of three ponds but not after 30 days (second trial). Methoprene treatment did not change the abundance of aquatic insects compared to untreated parts of the ponds.
5. Results of the Wright County Long Term Experiment indicate that following three years of application of methoprene to Michigan wetlands, there were no significant effects on zooplankton or bird populations. Significant reductions in benthic invertebrates were limited to chironomids (midges) which are closely related to mosquitoes.

**DISCUSSION:** The synthetic insect growth regulator methoprene has been studied for over 20 years. Review of the published and unpublished literature and the summary of information submitted by the registration applicant indicate that the only ecological effect of concern, as indicated by laboratory toxicity studies, is reduced reproduction of some non-target invertebrates such as *Daphnia* sp. Results of multi-year field studies in which methoprene was applied to Michigan wetlands as well as two historical studies involving the comparison of previously treated and untreated wetlands in the state of Michigan showed that zooplankton and avian reproduction and density were not affected by methoprene treatment; in one study, densities of some aquatic insects (chironomids and other benthic flies) were reduced by methoprene treatment. However, natural variability, the length of time over which the studies were conducted, and the response at other sites make the results of the field studies difficult to interpret.

These studies were not conducted according to prescribed procedures and should be considered supplementary. Studies address the ecological consequences of a long-term larvicidal program. Although natural variability occurs among sites and confounding factors such as fluctuating water levels were present, the Wright County Long Term Experiment indicates that, with the exception of reduced numbers of midges, there were no observable adverse ecological effects within the three-year treatment period. More precisely, there were no statistically significant decreases in cladoceran (which had been identified as sensitive non-target organisms) density or species richness between treated and untreated sites over the three-year treatment period. It is the opinion of the Scientific Peer Review Panel and the reviewer that the Wright County Long Term Experiment study should be continued for several more years.

The published literature indicate that methoprene is not persistent in the environment; however, application of slow release formulations or briquets ensure its presence over time. Because analysis of natural waters for methoprene is difficult due to interfering substances, some effort to measure concentrations in containers held under natural environmental conditions should be made.

The published literature also indicate that methoprene is practically nontoxic to mammals and birds and is not a reproductive toxicant. In addition, metabolism in a variety of species has been demonstrated. Therefore, the lack of effects on avian populations at the studied sites is not unexpected.



Although the Wright County Long Term Experiment was well summarized and data were provided, the original reports are necessary to perform a definitive evaluation.

### DISCUSSION OF INDIVIDUAL STUDIES:

#### 1. Wright County Historical Survey

**Method:** The purpose of this study was to compare 10 wetlands in the state of Michigan that had been treated with methoprene for two or more consecutive years with 30 wetlands outside the boundary of treatment. Comparisons were made in terms of effects on growth and reproduction of nesting red-winged blackbirds, (during one year) the yearly return rate of male red-winged blackbirds (two-year study), and on zooplankton and benthic invertebrates (one-year study). Zooplankton were collected with funnel-traps and benthic aquatic invertebrates were sampled with benthic cores.

**Results:** No differences between treated and untreated sites were detected in average clutch size, egg size, nestling growth rates, fledgling mass or fledgling ages of red-winged blackbirds. "Reproductive success was highly variable among sites, but appeared to be lower at sites where marsh wrens and yellow-headed blackbirds were present." Return rates of males were lower in the two years of study, but could not be correlated with an effect on the food web as determined by territory size, harem size, and egg and nest survival probabilities. No statistical differences were found between the treated and untreated sites for red-winged blackbird populations ( $p=0.05$ ) or invertebrate populations ( $p=0.05$ ); the raw data were not provided.

**Discussion:** Natural variability inherently makes comparisons among sites difficult in field studies. As noted by the authors, drought during the study year had lowered water levels, eliminating some areas and reducing densities of invertebrates in others with the result that treatment was difficult to distinguish from natural variation. The authors also noted that the treated sites had not been treated for very many consecutive years and the number of treatments per year in preceding years was relatively low. This study can be considered preliminary rather than definitive.

#### 2. North Metropolitan Area Bird Survey

**Method:** Terrestrial breeding birds in treated and untreated wetlands in three counties were censused. Eleven sites historically treated with methoprene and 23 sites historically treated with *Bacillus thuringiensis israelensis* (Bti) were paired with untreated sites on the basis of their area, shape, vegetation, and water regimes. Sites were selected using a double-blind approach. Bird populations were surveyed twice (mid-May to early July) using the variable circular plot technique. Nests of tree swallows in wooden nest boxes were monitored in seven matched pairs of sites during three years to estimate occupancy rates, clutch size, egg success, nestling growth rates, and fledgling success. The authors did not distinguish between methoprene and Bti-treated sites. Raw data were not provided.

**Results:** Of 26 different species of birds, only densities of yellow-headed blackbirds was significantly lower on the treated wetlands and their densities were negatively correlated with number of years of previous treatment. Growth of tree swallow nestlings was slightly retarded in treated wetlands during the first study year with nestlings from treated wetlands fledging about 2 days later,



but at approximately the same mass as those in non-treated wetlands; differences in fledgling age were not detected in the second and third years of the study.

**Discussion:** The study is not useful for ascertaining the effects of methoprene on bird populations as the investigators did not distinguish between methoprene and Bti-treated sites. In addition, as noted by the authors, many of the species censused are only weakly dependent on wetlands, effects on tree swallow fledgling growth were variable from year to year, and the small number of sites limited the power of the study to detect small effects of treatment. The study is not useful for ascertaining the effects of methoprene on bird populations.

### 3. Lake Maria Study

**Method:** Two wetland areas were trisected radially with curtains of polyolefin material. In April, one sector of a wetland was treated with a 150-day methoprene briquet (water concentration not stated/measured) and the other two sectors were treated with placebos. All sectors of the other wetland area received placebos. The different areas were sampled (time not stated) for zooplankton with funnel traps and for benthic invertebrates with benthic cores. A pre-treatment census was not mentioned.

**Results:** No statistically significant changes in densities of zooplankton, insects, or benthic invertebrates were observed between the treated and untreated sites.

**Discussion:** Few details of the study were provided. Aquatic organisms were not identified, but it can be assumed that they were similar to those in the accompanying studies. It appears that only one area was treated, although untreated areas were part of the same wetland. If present, larvicidal action should have been observable; however, it was noted by the authors that densities of the organisms of concern, benthic invertebrates, were too low to provide a rigorous test of the action of the larvicide. It was also stated that the dosage of methoprene was high enough to cause effects, but dosage was not stated. The study can be considered supplementary.

### 4. Mallard Duckling Study

**Methods:** Three ponds were bisected with double plastic barriers; randomly selected halves were treated with either methoprene briquets or placebos. Broods of 10 human-imprinted ducklings were placed in each wetland half and growth was observed for 5 (first trial) or 31 days (second trial) after initiation of treatment. Briquets stranded by receding water levels were replaced. Benthic organisms (food for the foraging ducklings) were sampled prior to and post-treatment. Floating traps were used to sample emerging insects.

**Results:** In the first trial ducklings from the treated site weighted less after 5 days of foraging than ducklings from the untreated site (no data provided); in the second trial, there was no difference in weights of ducklings between the treated and untreated halves. No significant differences in the density of benthic larvae or emerging adults were found between the sites. Data were not provided.

**Discussion:** No conclusions can be drawn from this study as weight differences of ducklings observed in the first trial were not evident in the second, longer trial. Treatment in the first trial was too short to affect insect densities and treatment during the second trial did not change the abundance of insects. Methoprene concentrations were not measured.



### 5. Wright County Long Term Experiment (WCLTE)

**Method:** This is a 5-year study (2-years pre-treatment and 3 years of treatment) of 17 wetland sites (9 reference sites and 8 methoprene treatment sites) in Wright County, Michigan. Six applications/year during spring and summer at rates ranging from 1.1 to 13.2 lbs/acre were made; the material was in the form of a 20-day release granule formulation. Treatments were monitored with bucket samplers placed in each wetland to measure the amount of material that was applied. Monitoring also included emergence success of mosquito larvae collected from treated and untreated sites. In addition to sampling for mosquitoes, populations of zooplankton and benthic invertebrates were sampled at 3-4 week intervals during the spring and summer of each year. Results from treatment sites were compared with reference sites using an ANOVA in three ways: date by date within each year, on a yearly basis across dates within each year, and averaged over the three treatment years ( $\alpha = 0.05$ ). Breeding birds were censused and blackbirds were examined for reproduction and behavior. Data were provided in graphs and tables.

**Results:** The presence of methoprene at the sites was indicated by the reduction in emergence of mosquito larvae during the last two years of the study. In 1992 emergences of collected larvae were 72% at the reference sites and 17% at the treated sites; the respective values in 1993 were 70% and 10%.

No effects on zooplankton occurred over the three years as indicated by species diversity, density, size, or reproduction. Although no effects on benthic invertebrates were detected during the first year of treatment, density and biomass were reduced compared with the control sites during the second and third year. Decreases at the treated sites were primarily due to reduced populations of chironomid larvae (midges) and other primitive flies. Midges were the most abundant and diverse group of benthic invertebrates at the sites.

Censuses of 19 breeding bird populations and a detailed study of red-winged blackbirds showed no consistent changes during the years of study. The censuses included three species that feed primarily on aquatic insects (soras, Virginia rails, and marsh wrens).

**Discussion:** Reduced densities of aquatic insects, particularly midges, which are closely related to mosquitoes, would be expected. Although the larvicidal program is aimed at mosquito control, the control of midges might not be considered detrimental to the environment unless some species of wetland birds are dependent on midges as their major food source. There were no declines in cladocerans which had been identified as sensitive non-target organism.

The red-winged blackbird is not dependent on wetlands for habitat and food but was the most abundant species and adequate for sampling. If possible, reproduction and development of the most abundant species of wetland species that feeds primarily on aquatic insects should be studied.

# DATA EVALUATION REPORT

(S)-METHOPRENE TECHNICAL

STUDY TYPE: LIFE-CYCLE - MYSID SHRIMP (72-4)

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831

Primary Reviewer:

Paul G. Forsyth, Ph.D.

Signature: *Robert H. Ross*

Date: 10-3-96

Secondary Reviewers:

Robert H. Ross, M.S., Group Leader

Signature: *RH Ross*

Date: 10-3-96

Sylvia S. Talmage, Ph.D., D.A.B.T.

Signature: *Sylvia S. Talmage*

Date: October 5, 1996

Quality Assurance:

Susan Chang, M.S.

Signature: *SSS Chang*

Date: 10/3/96

## Disclaimer

This Data Evaluation Report may have been altered by the Biopesticides and Pollution Prevention Division subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464



(S)-METHOPRENE TECHNICAL

Mysid Life-Cycle Study (72-4)

EPA Reviewer: Mark J. Perry  
Biopesticides and Pollution Prevention Division  
EPA Team Leader: Roy D. Sjoblad, Ph.D.  
Biopesticides and Pollution Prevention Division

Date: 10-22-96

Date: \_\_\_\_\_

**DATA EVALUATION REPORT**

**MRID# & TITLE OF STUDY:** MRID 44022101, (S)-Methoprene Technical - Chronic Toxicity to Mysids (*Mysidopsis bahia*) Under Flow-Through Conditions

**DP BARCODE:** D226999

**CASE:** 003099

**REG./FILE#:** 002724-00375

**CHEMICAL/BIOL#:** 105401 Methoprene

**COMPANY/SPONSOR:** Sandoz Agro, Inc., 1300 E. Touhy Avenue, Des Plaines, Illinois 60018

**TEST MATERIAL:** (S)-Methoprene Technical

**REVIEW CONCLUSION:** This study was conducted according to acceptable procedures and determined the following values for (S)-methoprene technical to mysid shrimp: LOEC of 25  $\mu\text{g a.i./L}$ , NOEC of 14  $\mu\text{g a.i./L}$ , and MATC > 14 and < 25  $\mu\text{g a.i./L}$  (geometric mean MATC = 19  $\mu\text{g a.i./L}$ ). This study was adequately conducted and provided useful data.

**RECOMMENDATIONS:** None

**ADEQUACY OF STUDY:** Core

**MATERIALS & METHODS:** The study procedures followed those of the Springborn Laboratories, Inc. (Wareham, MA) protocol entitled "(S)-Methoprene - Life-Cycle Toxicity Test with Mysids (*Mysidopsis bahia*), Following FIFRA Guideline 72-4" (Springborn Laboratories Protocol #:081295/FIFRA/530/s-methoprene [1995] and Protocol Amendment #1 [1995]). The study was conducted in accordance with GLP 40 CFR 160 with the exception of routine water screening and food analyses for pesticides, PCB's, and toxic metals. The water screening and food analyses were conducted using standard U.S. EPA procedures by Lancaster Laboratories (Lancaster, PA). No protocol deviations were noted and the study was acceptably conducted. The test material, (S)-Methoprene technical (Lot No. 5S1008, CAS# 40596-69-8), was received from Sandoz Agro, Inc. (Dallas, TX) and was stored frozen. The test material was an amber liquid with a purity of 95.311%, molecular weight of 310.5 g/mol, water solubility of 0.52 ppm, and vapor pressure of < 1 mm Hg. An analytical standard of (S)-Methoprene (Lot No. 95-24), was received from the same source and was an amber liquid with a purity of 95.21  $\pm$  0.01%. The analytical standard was also stored frozen.

The mysids ( $\leq 24$  hours old) used in these tests were obtained from laboratory cultures maintained at Springborn Laboratories (SLI Lot #95A107) and were kept in recirculated, filtered artificial seawater for 14 days prior to the test. Juvenile mysids ( $\leq 24$  hours old) were collected and fed brine shrimp (*Artemia salina*) nauplii, *ad libitum*, twice daily, with one feeding supplemented with Selco®, a liquid food supplement. Food sources were analyzed routinely and found to be acceptably free of pesticides, PCB's, and metals considered toxic to mysids.



Artificial seawater used as dilution water during these tests was prepared by the addition of a commercially prepared salt formula (hw-MARINEMIX®) to filtered soft freshwater having a hardness of 20 to 40 mg/L as  $\text{CaCO}_3$ , with a final salinity of  $25 \pm 3\text{‰}$ . The prepared dilution was aerated vigorously for approximately 24 hours, then allowed to aerate for an additional 24 hours prior to use. Routine analyses found no toxic concentrations of pesticides, PCBs, or toxic metals in the dilution water source. Mysids maintained in artificial seawater prepared from the same source as the artificial seawater used in this study have successfully survived and reproduced over several generations.

Nominal concentrations selected for the test material were 9.4, 19, 37, 75, and 150  $\mu\text{g a.i./L}$ . A 30 mg a.i./mL stock solution was prepared by dissolving 1.584 g of test material with acetone to volume in a 50 mL volumetric flask. Additionally, a 0.50 mL/mL solvent stock solution was prepared by diluting 50 mL of acetone with distilled water to volume in a 100 mL volumetric flask.

The life-cycle test was conducted using an exposure system consisting of a constant-flow serial diluter, a temperature-controlled water bath, and a set of 14 exposure aquaria (two per test concentration level). Each aquarium contained two mysid retention chambers made of glass Petri dishes covered with screen which were used to maintain non-paired mysids during the study. Pairing chambers, used to house sexually mature male and female organisms, were cylindrical glass jars having two screen-covered holes. The aquaria systems allowed for adequate solution exchange via siphon drains. The 150  $\mu\text{g a.i./L}$  nominal treatment was attained by delivering 0.0015 mL/min of the test material stock solution to a mixing chamber which also received 0.302 L/min of dilution water. The stock solution was proportionally diluted (50% dilution factor) to provide the remaining nominal test concentrations. A similar system was used to deliver the acetone stock solution to the diluter system of the solvent test chambers, providing an acetone concentration equivalent to the acetone concentration in the highest test solution. The solution exchange system operated at a rate of approximately 15 aquarium volume additions per day to provide a 90% test solution replacement rate of approximately 3.5 hours. The entire operating system was illuminated with fluorescent lighting for 16 hours daily followed by 8 hours darkness.

"Mysids,  $\leq 24$  hours old, were collected from the Springborn culture unit and divided among 28 beakers. The beakers contained culture water and were held in a waterbath maintained at  $25 \pm 2^\circ\text{C}$ . The organisms were impartially selected and distributed to the beakers by adding five organisms at a time to each beaker until each beaker contained 15 mysids. Each group of 15 mysids was then transferred to one of the 28 labeled retention chambers (two per aquarium). The test was initiated when the retention chambers were placed in their respective test aquaria. Each test aquarium contained two retention chambers, yielding 30 mysids per replicate vessel and 60 organisms for each treatment level and control."

Upon reaching sexual maturity (Day 15), mature male/female pairs within each exposure aquarium were transferred from the retention chambers to the 10 glass pairing jars (one pair per jar). The remaining mysids were all placed in one of the initial retention chambers within each aquarium and maintained for the duration of the chronic test. Male mysids from this pool were used to replace dead males removed from the paired groups. Females that died in pairing jars were not replaced. If development of brood pouches, distinguishing females from males, was delayed due to toxicant exposure, all test organisms were maintained in the retention chambers until maturity was observed or until test termination. Mysids were fed live brine shrimp (*Artemia salina*) nauplii twice daily. Before pairing, at least one of the daily feedings was enriched with Selco®. After pairing, the mysids were fed Selco®-enriched brine shrimp nauplii once every other day.



During the first 14 days, observations were made for mortality and any abnormal appearance or behavior. After pairing (Day 15), mortality of the paired mysids, the number of offspring produced by each female, and any abnormal appearance or behavior was recorded. Observations were made daily throughout the study. Dead mysids were removed and discarded.

At test termination, all mysids were sacrificed and measured for individual body length (nearest 0.1 mm) and total dry body weight (nearest 0.01 mg). Reproductive success was calculated for each replicate aquarium as the ratio of the total number of offspring produced to the total number of females contained within each chamber per reproductive day. The number of female reproductive days was determined as the number of days that an individual was alive, counting the day that offspring were first observed in any control (i.e., Day 18 represents reproductive day 1).

Daily measurements were made for water temperature, dissolved oxygen concentration, pH, and salinity in each replicate of each treatment. Samples were removed from each replicate test solution and control on days 0, 7, 14, 21, and 28 and analyzed for test material concentration.

Data from the paired and unpaired mysids were statistically analyzed for treatment effects. Endpoints analyzed for first generation ( $F_0$ ) mysids included survival, growth (i.e., body weights and lengths), and reproduction. Reproductive success was determined only for the paired organisms. Bartlett's Test was used to test for homogeneity of variance (99% certainty level). Student's t-test was conducted for each endpoint to compare solvent and negative controls, resulting in no significant difference. Therefore, solvent and negative control endpoints were pooled for the remaining comparisons between controls and treatments. The Williams' Test was used to determine treatment level effects (95% certainty level). The Maximum-Acceptable-Toxicant-Concentration (MATC), or the theoretical threshold concentration of the test material expected to produce no deleterious effects to mysids, was estimated at the 95% certainty level. Also determined were the Lowest-Observed-Effect Concentration (LOEC) and the No-Observed-Effect Concentration (NOEC).

**REPORTED RESULTS:** Water quality parameters measured during the 28-day exposure remained within acceptable limits. Analyses of test material concentrations in the aquaria exhibited consistency between replicates and sampling intervals and the expected concentration gradient across treatment levels was maintained throughout the 28-day test. However, mean measured concentrations ranged from 66 to 77% of the nominal concentrations and defined the concentrations tested as 7.2, 14, 25, 50, and 98  $\mu\text{g a.i./L}$ . Coefficients of variation averaged 15% for all mean measured concentrations.

Survivals of the  $F_0$  mysids were 90 and 92% for the control and solvent control, respectively, with no statistical difference between the two (pooled control survival = 91%). Survivals of 78, 78, 82, 83, and 57% were observed for mysids exposed to mean measured test material levels of 7.2, 14, 25, 50, and 98  $\mu\text{g a.i./L}$ , respectively. Only the 98  $\mu\text{g a.i./L}$  concentration was determined to be statistically different from the pooled control results. For this reason, results for that treatment were eliminated from further chronic statistical analyses.

No statistical difference was observed between control and solvent control mysids for reproductive success (0.6 and 0.39 offspring/female/reproductive day, respectively) and these groups were pooled (mean = 0.50 offspring/female/reproductive day). Mysid reproduction in the treatment levels that did not adversely affect survival, i.e., 7.2, 14, 25, and 50  $\mu\text{g a.i./L}$ , ranged from 0.22 to 0.45 offspring/female/reproductive day and were determined not to be significantly different from the pooled control organisms with respect to reproductive success.



The mean body lengths of male and female control mysids were 7.0 and 6.9 mm, respectively, while the solvent control mysids measured 7.2 and 7.0 mm for males and females, respectively. The control and solvent control body length measurements were not statistically different, and the pooled lengths for control males and females were 7.1 and 7.0, respectively. For exposure concentrations to the test material of 7.2, 14, 25, and 50  $\mu\text{g a.i./L}$ , the respective body lengths for male mysids were 7.1, 7.2, 7.2 and 7.1 mm, while the respective body lengths for females were 7.2, 7.1, 7.2, and 6.9 mm. Both male and female body lengths were not statistically different from the pooled control body lengths. These data indicate that the test material "at levels  $\leq 5.0 \mu\text{g a.i./L}$ " did not adversely affect organism growth based on body length. Obviously, this should read "at levels  $\leq 50 \mu\text{g a.i./L}$ ".

The mean body weights for the control and solvent control male mysids were 0.88 and 0.82 mg, respectively, while those for females were 1.0 and 0.90 mg, respectively. There were no statistical differences between control and solvent control groups for either males or females, allowing for pooled averages of 0.85 and 0.95 mg for males and females, respectively. For exposure concentrations to the test material of 7.2, 14, 25, and 50  $\mu\text{g a.i./L}$ , the respective dry body weights for male mysids were 0.78, 0.82, 0.75, and 0.78 mg, while respective dry body weights for females were 0.93, 0.93, 0.93, and 0.81 mg. Statistically significant reduced dry body weights occurred in exposure concentrations to the test material of 25 and 50  $\mu\text{g a.i./L}$  for males and 50  $\mu\text{g a.i./L}$  for females.

"Based on the results of this study, the LOEC and NOEC of (S)-Methoprene technical for mysid survival, reproductive success and growth (total body length and dry weight) was determined. Dry body weight of male mysids was determined to be the most sensitive indicator of toxicity of (S)-Methoprene technical to mysids. The LOEC and NOEC, based on male dry body weight, was 25 and 14  $\mu\text{g a.i./L}$ , respectively. The Maximum-Acceptable-Toxicant Concentration (MATC) was calculated to be  $> 14$  and  $< 25 \mu\text{g a.i./L}$  (Geometric Mean, MATC = 19  $\mu\text{g a.i./L}$ ). These data provided a MATC which corroborated the conservatively estimated MATC (i.e., 24  $\mu\text{g a.i./L}$ ) determined during previously conducted life-cycle tests (SLI Report #92-11-4518)."

**DISCUSSION:** This study was conducted following acceptable procedures outlined in FIFRA Guideline 72-4, Subdivision E of the U.S. EPA Pesticide Assessment Guidelines (1982). This study determined the following values for (S)-methoprene technical to mysid shrimp: LOEC of 25  $\mu\text{g a.i./L}$ , NOEC of 14  $\mu\text{g a.i./L}$ , and MATC  $> 14$  and  $< 25 \mu\text{g a.i./L}$  (geometric mean MATC = 19  $\mu\text{g a.i./L}$ ). These values are based on the dry body weight for male mysids, which was determined to be the most sensitive performance criterion measured in these tests. The mortality data (presented as "Percent Survival") were reported to be significant only at the 98  $\mu\text{g a.i./L}$  level, and sublethal data at this level were not used in statistical calculations.

Although mortality was measured, no  $\text{LC}_{50}$  was calculated since 50% mortality was never achieved, nor did the data seem to follow a dose-response curve, i.e., percent survival was lower at the two lower treatment concentrations (78% for both) than at the next two higher treatment concentrations (82 and 83%) but lowest at the highest concentration of 98  $\mu\text{g a.i./L}$  (57%). The survival data shown in Table 1 are the actual percentages measured in each aquarium, with the mean given for the two aquaria per concentration. The reduction in survival does not follow a dose-response fashion, except that the greatest mortality occurs in the highest treatment concentration level. Although the Williams' Test showed no significant difference in survival between each of the treatments and the pooled controls (at  $\leq 50 \mu\text{g a.i./L}$ ), the use of only two data points (per treatment) does not give a standard deviation and is of questionable statistical validity.



The authors report no significant effect of the test material on reproductive success in mysids. However, the reproductive data shown in Table 1 is presented in a similar fashion to the survival data. When the number of reproducing females and the number of reproductive days are divided out, all of the reproductive data within an aquarium is reduced to a single number. Again, the use of only two values is of questionable statistical validity. The reviewer repeated the statistical analyses of the author regarding survival and reproduction and concurs with the author's conclusion.

TABLE 1. Summary of the first generation ( $F_0$ ) survival and reproductive success (offspring/female/reproductive day) during the 28-day life-cycle exposure of mysids (*Mysidopsis bahia*) to (S)-Methoprene Technical

Mean Measured Concentration $\mu\text{g a.i./L}$	Replicate	Percent Survival <sup>a</sup>	Reproductive Success <sup>a</sup>
Control	A	90	0.41
	B	90	0.79
	Mean	90	0.60
Solvent Control	A	90	0.33
	B	93	0.44
	Mean	92	0.39
Pooled Control <sup>b</sup>	Mean	91	0.50
7.2	A	73	0.42
	B	83	0.29
	Mean	78	0.36
14	A	73	0.44
	B	83	0.46
	Mean	78	0.45
25	A	87	0.49
	B	77	0.25
	Mean	82	0.37
50	A	83	0.18
	B	83	0.25
	Mean	83	0.22
98	A	60	0.083
	B	53	0.0094
	Mean	57 <sup>c</sup>	0.046 <sup>d</sup>

Data taken from Table 3, p. 34, MRID 44022101.

<sup>a</sup> Values presented have been rounded to two significant figures.

<sup>b</sup> Since control and solvent control data were not determined to be significantly different, all treatment data were compared to the pooled control data.

<sup>c</sup> Significantly different ( $p \leq 0.05$ ) from the pooled control (Williams' Test).

<sup>d</sup> Since organism survival was adversely affected, this treatment level was excluded from statistical analysis to determine treatment effects for body length, body weight, and reproductive success.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 23 1986

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**Memorandum**

**Subject:** Review of Ecotoxicity Data Submitted in Compliance with the Methoprene RED (DP Barcode D226999, Case No. 003099, MRIDs 440221-01 and 440221-02)

**From:** Mark J. Perry, Biologist  
Biopesticides and Pollution Prevention Division (7501W)

**Thru:** J. Thomas McClintock, Team Leader  
Biopesticides and Pollution Prevention Division (7501W)

**To:** Willie Nelson, Regulatory Action Leader  
Biopesticides and Pollution Prevention Division (7501W)

*Handwritten notes:*  
Mark J. Perry  
10/12/86  
J.T.M. - 10/13/86

**Action Requested**

Sandoz Agro, Inc. submitted a chronic toxicity study performed with mysid shrimp (guideline reference 72-4) and a study evaluating non-target effects in metropolitan wetland areas (non-guideline). Both studies were performed with technical methoprene and were submitted in response to the methoprene RED. The non-guideline study was required by the Agency prior to reclassification of methoprene as a biochemical. This study also evaluated the use of *B. thuringiensis israelensis* as a mosquito larvicide.

**Results/Conclusion**

The non-target effects in metropolitan wetland areas (non-guideline) study is classified supplemental; it was not conducted following GLP regulations 40 CFR 160. Although the study may provide useful information, it does not satisfy the data requirement. In general, the results of the study indicate that, with field use of methoprene in wetlands, adverse ecological effects on non-target organisms were either not present or were unmeasurable due to natural variability or study design constraints.

The chronic toxicity (72-4) study was conducted according to acceptable procedures and determined the following values for methoprene technical to mysid shrimp (*Mysidopsis bahia*): LOEC of 25  $\mu\text{g a.i./L}$ , NOEC of 14  $\mu\text{g a.i./L}$ , and MATC  $> 14$  and  $< 25 \mu\text{g a.i./L}$  (geometric mean MATC = 19  $\mu\text{g a.i./L}$ ). This study was adequately conducted (core) and provides acceptable data. Although the results are valid, the expected effect on aquatic invertebrates cannot be evaluated without the estimated environmental concentration (EEC) determined from the recommended use levels for this product.

# DATA EVALUATION REPORT

METHOPRENE

STUDY TYPE: NON-GUIDELINE STUDY

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
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Primary Reviewer:

Sylvia S. Talmage, Ph.D., D.A.B.T.

Signature: Sylvia S. Talmage  
Date: October 2, 1996

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Robert H. Ross, M.S., Group Leader

Signature: RHR  
Date: 10-3-96

Paul G. Forsyth, Ph.D.

Signature: Paul G. Forsyth  
Date: 10-3-96

Quality Assurance:

Susan Chang, M.S.

Signature: SSC  
Date: 10/3/96

## Disclaimer

This Data Evaluation Report may have been altered by the Biopesticides and Pollution Prevention Division subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464



**METHOPRENE**

Non-Guideline Study

EPA Reviewer: Mark J. Perry  
Biopesticides and Pollution Prevention Division  
EPA Team Leader: Roy D. Sjoblad, Ph.D.  
Biopesticides and Pollution Prevention Division

Date: 10-22-96

Date: 10/23/96

**DATA EVALUATION REPORT**

**MRID# & TITLE OF STUDY:** MRID 44022102, An Assessment of the Non-Target Effects of the Mosquito Larvicides, Bti and Methoprene, in Metropolitan Area Wetlands

**DB BARCODE:** D226999  
**REG./FILE#:** 002724-00375

**CASE:** 003099  
**CHEMICAL/BIOL#:** 105401 Methoprene

**COMPANY/SPONSOR:** Sandoz Agro, Inc.

**TEST MATERIAL:** Methoprene

**REVIEW CONCLUSION:** This non-guideline study is classified supplementary; it was not conducted following GLP regulations 40 CFR 160. The original data, particularly for the Wright County Long Term Experiment, should be provided in order to perform a more definitive evaluation. In general, the results of the studies indicated that, with field use of methoprene in wetlands, adverse ecological effects on non-target organisms were either not present or were unmeasurable due to natural variability or study design constraints.

**RECOMMENDATIONS:** The sponsor should provide copies of the original unpublished laboratory and field studies for review. The Wright County Long Term Experiment could serve as a Tier IV Simulated or Actual Field Testing for Aquatic Organisms (Guideline M 154A-34) if the entire report including raw data were submitted. A combination of the Wright County Long Term Experiment and the Wright County Historical Survey could serve as a Tier IV Simulated or Actual Field Testing for Birds (Subdivision M, Guideline 154A-33) if the entire report including raw data were submitted.

**ADEQUACY OF STUDY:** Supplementary; this study was not intended to fulfill a guideline requirement but was intended to support reregistration of methoprene.

**MATERIALS & METHODS:** The study summarizes five field studies in which the effects of the application of methoprene to Michigan wetlands on non-target organisms was evaluated. The individual studies were suggested and sponsored by the Scientific Peer Review Panel of the Metropolitan Mosquito Control District and addressed the long-term ecological effects of a larvicidal program. As such, these studies did not follow the principles of GLP as outlined in 40 CFR Part 160. Additional methodology is summarized under the discussion of the individual studies.

**REPORTED RESULTS:** The results were provided as summaries of the five individual studies.

1. In the Wright County Historical Survey, no statistical differences in growth, reproduction, or return rates of red-winged blackbird populations or species composition and density of invertebrates were found between wetlands treated with methoprene and untreated sites.



2. In the North Metropolitan Area Bird Survey, observed differences in bird populations between untreated wetlands and wetlands historically treated with either methoprene or another larvicide were not clearly treatment related. No distinction between methoprene-treated sites and sites treated with the other larvicide was made.
3. In the Lake Maria Study, no statistically significant changes in densities of zooplankton, insects, or benthic invertebrates were observed between the methoprene-treated and untreated areas of Lake Maria. However, densities were too low for the statistical evaluation to be rigorous.
4. In the Mallard Duckling Study, differences in duckling weight were observed after five days (first trial) between treated and untreated sides of three ponds but not after 30 days (second trial). Methoprene treatment did not change the abundance of aquatic insects compared to untreated parts of the ponds.
5. Results of the Wright County Long Term Experiment indicate that following three years of application of methoprene to Michigan wetlands, there were no significant effects on zooplankton or bird populations. Significant reductions in benthic invertebrates were limited to chironomids (midges) which are closely related to mosquitoes.

**DISCUSSION:** The synthetic insect growth regulator methoprene has been studied for over 20 years. Review of the published and unpublished literature and the summary of information submitted by the registration applicant indicate that the only ecological effect of concern, as indicated by laboratory toxicity studies, is reduced reproduction of some non-target invertebrates such as *Daphnia* sp. Results of multi-year field studies in which methoprene was applied to Michigan wetlands as well as two historical studies involving the comparison of previously treated and untreated wetlands in the state of Michigan showed that zooplankton and avian reproduction and density were not affected by methoprene treatment; in one study, densities of some aquatic insects (chironomids and other benthic flies) were reduced by methoprene treatment. However, natural variability, the length of time over which the studies were conducted, and the response at other sites make the results of the field studies difficult to interpret.

These studies were not conducted according to prescribed procedures and should be considered supplementary. Studies address the ecological consequences of a long-term larvicidal program. Although natural variability occurs among sites and confounding factors such as fluctuating water levels were present, the Wright County Long Term Experiment indicates that, with the exception of reduced numbers of midges, there were no observable adverse ecological effects within the three-year treatment period. More precisely, there were no statistically significant decreases in cladoceran (which had been identified as sensitive non-target organisms) density or species richness between treated and untreated sites over the three-year treatment period. It is the opinion of the Scientific Peer Review Panel and the reviewer that the Wright County Long Term Experiment study should be continued for several more years.

The published literature indicate that methoprene is not persistent in the environment; however, application of slow release formulations or briquets ensure its presence over time. Because analysis of natural waters for methoprene is difficult due to interfering substances, some effort to measure concentrations in containers held under natural environmental conditions should be made.

The published literature also indicate that methoprene is practically nontoxic to mammals and birds and is not a reproductive toxicant. In addition, metabolism in a variety of species has been demonstrated. Therefore, the lack of effects on avian populations at the studied sites is not unexpected.



Although the Wright County Long Term Experiment was well summarized and data were provided, the original reports are necessary to perform a definitive evaluation.

### DISCUSSION OF INDIVIDUAL STUDIES:

#### 1. Wright County Historical Survey

**Method:** The purpose of this study was to compare 10 wetlands in the state of Michigan that had been treated with methoprene for two or more consecutive years with 30 wetlands outside the boundary of treatment. Comparisons were made in terms of effects on growth and reproduction of nesting red-winged blackbirds, (during one year) the yearly return rate of male red-winged blackbirds (two-year study), and on zooplankton and benthic invertebrates (one-year study). Zooplankton were collected with funnel-traps and benthic aquatic invertebrates were sampled with benthic cores.

**Results:** No differences between treated and untreated sites were detected in average clutch size, egg size, nestling growth rates, fledgling mass or fledgling ages of red-winged blackbirds. "Reproductive success was highly variable among sites, but appeared to be lower at sites where marsh wrens and yellow-headed blackbirds were present." Return rates of males were lower in the two years of study, but could not be correlated with an effect on the food web as determined by territory size, harem size, and egg and nest survival probabilities. No statistical differences were found between the treated and untreated sites for red-winged blackbird populations ( $p=0.05$ ) or invertebrate populations ( $p=0.05$ ); the raw data were not provided.

**Discussion:** Natural variability inherently makes comparisons among sites difficult in field studies. As noted by the authors, drought during the study year had lowered water levels, eliminating some areas and reducing densities of invertebrates in others with the result that treatment was difficult to distinguish from natural variation. The authors also noted that the treated sites had not been treated for very many consecutive years and the number of treatments per year in preceding years was relatively low. This study can be considered preliminary rather than definitive.

#### 2. North Metropolitan Area Bird Survey

**Method:** Terrestrial breeding birds in treated and untreated wetlands in three counties were censused. Eleven sites historically treated with methoprene and 23 sites historically treated with *Bacillus thuringiensis israelensis* (Bti) were paired with untreated sites on the basis of their area, shape, vegetation, and water regimes. Sites were selected using a double-blind approach. Bird populations were surveyed twice (mid-May to early July) using the variable circular plot technique. Nests of tree swallows in wooden nest boxes were monitored in seven matched pairs of sites during three years to estimate occupancy rates, clutch size, egg success, nestling growth rates, and fledgling success. The authors did not distinguish between methoprene and Bti-treated sites. Raw data were not provided.

**Results:** Of 26 different species of birds, only densities of yellow-headed blackbirds was significantly lower on the treated wetlands and their densities were negatively correlated with number of years of previous treatment. Growth of tree swallow nestlings was slightly retarded in treated wetlands during the first study year with nestlings from treated wetlands fledgling about 2 days later,



but at approximately the same mass as those in non-treated wetlands; differences in fledgling age were not detected in the second and third years of the study.

**Discussion:** The study is not useful for ascertaining the effects of methoprene on bird populations as the investigators did not distinguish between methoprene and Bti-treated sites. In addition, as noted by the authors, many of the species censused are only weakly dependent on wetlands, effects on tree swallow fledgling growth were variable from year to year, and the small number of sites limited the power of the study to detect small effects of treatment. The study is not useful for ascertaining the effects of methoprene on bird populations.

### 3. Lake Maria Study

**Method:** Two wetland areas were trisected radially with curtains of polyolefin material. In April, one sector of a wetland was treated with a 150-day methoprene briquet (water concentration not stated/measured) and the other two sectors were treated with placebos. All sectors of the other wetland area received placebos. The different areas were sampled (time not stated) for zooplankton with funnel traps and for benthic invertebrates with benthic cores. A pre-treatment census was not mentioned.

**Results:** No statistically significant changes in densities of zooplankton, insects, or benthic invertebrates were observed between the treated and untreated sites.

**Discussion:** Few details of the study were provided. Aquatic organisms were not identified, but it can be assumed that they were similar to those in the accompanying studies. It appears that only one area was treated, although untreated areas were part of the same wetland. If present, larvicidal action should have been observable; however, it was noted by the authors that densities of the organisms of concern, benthic invertebrates, were too low to provide a rigorous test of the action of the larvicide. It was also stated that the dosage of methoprene was high enough to cause effects, but dosage was not stated. The study can be considered supplementary.

### 4. Mallard Duckling Study

**Methods:** Three ponds were bisected with double plastic barriers; randomly selected halves were treated with either methoprene briquets or placebos. Broods of 10 human-imprinted ducklings were placed in each wetland half and growth was observed for 5 (first trial) or 31 days (second trial) after initiation of treatment. Briquets stranded by receding water levels were replaced. Benthic organisms (food for the foraging ducklings) were sampled prior to and post-treatment. Floating traps were used to sample emerging insects.

**Results:** In the first trial ducklings from the treated site weighted less after 5 days of foraging than ducklings from the untreated site (no data provided); in the second trial, there was no difference in weights of ducklings between the treated and untreated halves. No significant differences in the density of benthic larvae or emerging adults were found between the sites. Data were not provided.

**Discussion:** No conclusions can be drawn from this study as weight differences of ducklings observed in the first trial were not evident in the second, longer trial. Treatment in the first trial was too short to affect insect densities and treatment during the second trial did not change the abundance of insects. Methoprene concentrations were not measured.



### 5. Wright County Long Term Experiment (WCLTE)

**Method:** This is a 5-year study (2-years pre-treatment and 3 years of treatment) of 17 wetland sites (9 reference sites and 8 methoprene treatment sites) in Wright County, Michigan. Six applications/year during spring and summer at rates ranging from 1.1 to 13.2 lbs/acre were made; the material was in the form of a 20-day release granule formulation. Treatments were monitored with bucket samplers placed in each wetland to measure the amount of material that was applied. Monitoring also included emergence success of mosquito larvae collected from treated and untreated sites. In addition to sampling for mosquitoes, populations of zooplankton and benthic invertebrates were sampled at 3-4 week intervals during the spring and summer of each year. Results from treatment sites were compared with reference sites using an ANOVA in three ways: date by date within each year, on a yearly basis across dates within each year, and averaged over the three treatment years ( $\alpha = 0.05$ ). Breeding birds were censused and blackbirds were examined for reproduction and behavior. Data were provided in graphs and tables.

**Results:** The presence of methoprene at the sites was indicated by the reduction in emergence of mosquito larvae during the last two years of the study. In 1992 emergences of collected larvae were 72% at the reference sites and 17% at the treated sites; the respective values in 1993 were 70% and 10%.

No effects on zooplankton occurred over the three years as indicated by species diversity, density, size, or reproduction. Although no effects on benthic invertebrates were detected during the first year of treatment, density and biomass were reduced compared with the control sites during the second and third year. Decreases at the treated sites were primarily due to reduced populations of chironomid larvae (midges) and other primitive flies. Midges were the most abundant and diverse group of benthic invertebrates at the sites.

Censuses of 19 breeding bird populations and a detailed study of red-winged blackbirds showed no consistent changes during the years of study. The censuses included three species that feed primarily on aquatic insects (soras, Virginia rails, and marsh wrens).

**Discussion:** Reduced densities of aquatic insects, particularly midges, which are closely related to mosquitoes, would be expected. Although the larvicidal program is aimed at mosquito control, the control of midges might not be considered detrimental to the environment unless some species of wetland birds are dependent on midges as their major food source. There were no declines in cladocerans which had been identified as sensitive non-target organism.

The red-winged blackbird is not dependent on wetlands for habitat and food but was the most abundant species and adequate for sampling. If possible, reproduction and development of the most abundant species of wetland species that feeds primarily on aquatic insects should be studied.

# DATA EVALUATION REPORT

(S)-METHOPRENE TECHNICAL

STUDY TYPE: LIFE-CYCLE - MYSID SHRIMP (72-4)

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831

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Date: October 5, 1996

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Date: 10/3/96

## Disclaimer

This Data Evaluation Report may have been altered by the Biopesticides and Pollution Prevention Division subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464



(S)-METHOPRENE TECHNICAL

Mysid Life-Cycle Study (72-4)

EPA Reviewer: Mark J. Perry  
Biopesticides and Pollution Prevention Division  
EPA Team Leader: Roy D. Sjoblad, Ph.D.  
Biopesticides and Pollution Prevention Division

Date: 10-22-96

Date: \_\_\_\_\_

**DATA EVALUATION REPORT**

**MRID# & TITLE OF STUDY:** MRID 44022101, (S)-Methoprene Technical - Chronic Toxicity to Mysids (*Mysidopsis bahia*) Under Flow-Through Conditions

**DP BARCODE:** D226999

**CASE:** 003099

**REG./FILE#:** 002724-00375

**CHEMICAL/BIOLOGICAL#:** 105401 Methoprene

**COMPANY/SPONSOR:** Sandoz Agro, Inc., 1300 E. Touhy Avenue, Des Plaines, Illinois 60018

**TEST MATERIAL:** (S)-Methoprene Technical

**REVIEW CONCLUSION:** This study was conducted according to acceptable procedures and determined the following values for (S)-methoprene technical to mysid shrimp: LOEC of 25  $\mu\text{g a.i./L}$ , NOEC of 14  $\mu\text{g a.i./L}$ , and MATC > 14 and < 25  $\mu\text{g a.i./L}$  (geometric mean MATC = 19  $\mu\text{g a.i./L}$ ). This study was adequately conducted and provided useful data.

**RECOMMENDATIONS:** None

**ADEQUACY OF STUDY:** Core

**MATERIALS & METHODS:** The study procedures followed those of the Springborn Laboratories, Inc. (Wareham, MA) protocol entitled "(S)-Methoprene - Life-Cycle Toxicity Test with Mysids (*Mysidopsis bahia*), Following FIFRA Guideline 72-4" (Springborn Laboratories Protocol #:081295/FIFRA/530/s-methoprene [1995] and Protocol Amendment #1 [1995]). The study was conducted in accordance with GLP 40 CFR 160 with the exception of routine water screening and food analyses for pesticides, PCB's, and toxic metals. The water screening and food analyses were conducted using standard U.S. EPA procedures by Lancaster Laboratories (Lancaster, PA). No protocol deviations were noted and the study was acceptably conducted. The test material, (S)-Methoprene technical (Lot No. 5S1008, CAS# 40596-69-8), was received from Sandoz Agro, Inc. (Dallas, TX) and was stored frozen. The test material was an amber liquid with a purity of 95.311%, molecular weight of 310.5 g/mol, water solubility of 0.52 ppm, and vapor pressure of < 1 mm Hg. An analytical standard of (S)-Methoprene (Lot No. 95-24) was received from the same source and was an amber liquid with a purity of 95.21  $\pm$  0.01%. The analytical standard was also stored frozen.

The mysids ( $\leq$  24 hours old) used in these tests were obtained from laboratory cultures maintained at Springborn Laboratories (SLI Lot #95A107) and were kept in recirculated, filtered artificial seawater for 14 days prior to the test. Juvenile mysids ( $\leq$  24 hours old) were collected and fed brine shrimp (*Artemia salina*) nauplii, *ad libitum*, twice daily, with one feeding supplemented with Selco®, a liquid food supplement. Food sources were analyzed routinely and found to be acceptably free of pesticides, PCB's, and metals considered toxic to mysids.



Artificial seawater used as dilution water during these tests was prepared by the addition of a commercially prepared salt formula (hw-MARINEMIX®) to filtered soft freshwater having a hardness of 20 to 40 mg/L as CaCO<sub>3</sub>, with a final salinity of  $25 \pm 3\text{‰}$ . The prepared dilution was aerated vigorously for approximately 24 hours, then allowed to aerate for an additional 24 hours prior to use. Routine analyses found no toxic concentrations of pesticides, PCBs, or toxic metals in the dilution water source. Mysids maintained in artificial seawater prepared from the same source as the artificial seawater used in this study have successfully survived and reproduced over several generations.

Nominal concentrations selected for the test material were 9.4, 19, 37, 75, and 150 µg a.i./L. A 30 mg a.i./mL stock solution was prepared by dissolving 1.584 g of test material with acetone to volume in a 50 mL volumetric flask. Additionally, a 0.50 mL/mL solvent stock solution was prepared by diluting 50 mL of acetone with distilled water to volume in a 100 mL volumetric flask.

The life-cycle test was conducted using an exposure system consisting of a constant-flow serial diluter, a temperature-controlled water bath, and a set of 14 exposure aquaria (two per test concentration level). Each aquarium contained two mysid retention chambers made of glass Petri dishes covered with screen which were used to maintain non-paired mysids during the study. Pairing chambers, used to house sexually mature male and female organisms, were cylindrical glass jars having two screen-covered holes. The aquaria systems allowed for adequate solution exchange via siphon drains. The 150 µg a.i./L nominal treatment was attained by delivering 0.0015 mL/min of the test material stock solution to a mixing chamber which also received 0.302 L/min of dilution water. The stock solution was proportionally diluted (50% dilution factor) to provide the remaining nominal test concentrations. A similar system was used to deliver the acetone stock solution to the diluter system of the solvent test chambers, providing an acetone concentration equivalent to the acetone concentration in the highest test solution. The solution exchange system operated at a rate of approximately 15 aquarium volume additions per day to provide a 90% test solution replacement rate of approximately 3.5 hours. The entire operating system was illuminated with fluorescent lighting for 16 hours daily followed by 8 hours darkness.

"Mysids,  $\leq 24$  hours old, were collected from the Springborn culture unit and divided among 28 beakers. The beakers contained culture water and were held in a waterbath maintained at  $25 \pm 2^\circ\text{C}$ . The organisms were impartially selected and distributed to the beakers by adding five organisms at a time to each beaker until each beaker contained 15 mysids. Each group of 15 mysids was then transferred to one of the 28 labeled retention chambers (two per aquarium). The test was initiated when the retention chambers were placed in their respective test aquaria. Each test aquarium contained two retention chambers, yielding 30 mysids per replicate vessel and 60 organisms for each treatment level and control."

Upon reaching sexual maturity (Day 15), mature male/female pairs within each exposure aquarium were transferred from the retention chambers to the 10 glass pairing jars (one pair per jar). The remaining mysids were all placed in one of the initial retention chambers within each aquarium and maintained for the duration of the chronic test. Male mysids from this pool were used to replace dead males removed from the paired groups. Females that died in pairing jars were not replaced. If development of brood pouches, distinguishing females from males, was delayed due to toxicant exposure, all test organisms were maintained in the retention chambers until maturity was observed or until test termination. Mysids were fed live brine shrimp (*Artemia salina*) nauplii twice daily. Before pairing, at least one of the daily feedings was enriched with Selco®. After pairing, the mysids were fed Selco®-enriched brine shrimp nauplii once every other day.



During the first 14 days, observations were made for mortality and any abnormal appearance or behavior. After pairing (Day 15), mortality of the paired mysids, the number of offspring produced by each female, and any abnormal appearance or behavior was recorded. Observations were made daily throughout the study. Dead mysids were removed and discarded.

At test termination, all mysids were sacrificed and measured for individual body length (nearest 0.1 mm) and total dry body weight (nearest 0.01 mg). Reproductive success was calculated for each replicate aquarium as the ratio of the total number of offspring produced to the total number of females contained within each chamber per reproductive day. The number of female reproductive days was determined as the number of days that an individual was alive, counting the day that offspring were first observed in any control (i.e., Day 18 represents reproductive day 1).

Daily measurements were made for water temperature, dissolved oxygen concentration, pH, and salinity in each replicate of each treatment. Samples were removed from each replicate test solution and control on days 0, 7, 14, 21, and 28 and analyzed for test material concentration.

Data from the paired and unpaired mysids were statistically analyzed for treatment effects. Endpoints analyzed for first generation ( $F_0$ ) mysids included survival, growth (i.e., body weights and lengths), and reproduction. Reproductive success was determined only for the paired organisms. Bartlett's Test was used to test for homogeneity of variance (99% certainty level). Student's t-test was conducted for each endpoint to compare solvent and negative controls, resulting in no significant difference. Therefore, solvent and negative control endpoints were pooled for the remaining comparisons between controls and treatments. The Williams' Test was used to determine treatment level effects (95% certainty level). The Maximum-Acceptable-Toxicant-Concentration (MATC), or the theoretical threshold concentration of the test material expected to produce no deleterious effects to mysids, was estimated at the 95% certainty level. Also determined were the Lowest-Observed-Effect Concentration (LOEC) and the No-Observed-Effect Concentration (NOEC).

**REPORTED RESULTS:** Water quality parameters measured during the 28-day exposure remained within acceptable limits. Analyses of test material concentrations in the aquaria exhibited consistency between replicates and sampling intervals and the expected concentration gradient across treatment levels was maintained throughout the 28-day test. However, mean measured concentrations ranged from 66 to 77% of the nominal concentrations and defined the concentrations tested as 7.2, 14, 25, 50, and 98  $\mu\text{g a.i./L}$ . Coefficients of variation averaged 15% for all mean measured concentrations.

Survivals of the  $F_0$  mysids were 90 and 92% for the control and solvent control, respectively, with no statistical difference between the two (pooled control survival = 91%). Survivals of 78, 78, 82, 83, and 57% were observed for mysids exposed to mean measured test material levels of 7.2, 14, 25, 50, and 98  $\mu\text{g a.i./L}$ , respectively. Only the 98  $\mu\text{g a.i./L}$  concentration was determined to be statistically different from the pooled control results. For this reason, results for that treatment were eliminated from further chronic statistical analyses.

No statistical difference was observed between control and solvent control mysids for reproductive success (0.6 and 0.39 offspring/female/reproductive day, respectively) and these groups were pooled (mean = 0.50 offspring/female/reproductive day). Mysid reproduction in the treatment levels that did not adversely affect survival, i.e., 7.2, 14, 25, and 50  $\mu\text{g a.i./L}$ , ranged from 0.22 to 0.45 offspring/female/reproductive day and were determined not to be significantly different from the pooled control organisms with respect to reproductive success.



The mean body lengths of male and female control mysids were 7.0 and 6.9 mm, respectively, while the solvent control mysids measured 7.2 and 7.0 mm for males and females, respectively. The control and solvent control body length measurements were not statistically different, and the pooled lengths for control males and females were 7.1 and 7.0, respectively. For exposure concentrations to the test material of 7.2, 14, 25, and 50  $\mu\text{g a.i./L}$ , the respective body lengths for male mysids were 7.1, 7.2, 7.2 and 7.1 mm, while the respective body lengths for females were 7.2, 7.1, 7.2, and 6.9 mm. Both male and female body lengths were not statistically different from the pooled control body lengths. These data indicate that the test material "at levels  $\leq 5.0 \mu\text{g a.i./L}$ " did not adversely affect organism growth based on body length. Obviously, this should read "at levels  $\leq 50 \mu\text{g a.i./L}$ ".

The mean body weights for the control and solvent control male mysids were 0.88 and 0.82 mg, respectively, while those for females were 1.0 and 0.90 mg, respectively. There were no statistical differences between control and solvent control groups for either males or females, allowing for pooled averages of 0.85 and 0.95 mg for males and females, respectively. For exposure concentrations to the test material of 7.2, 14, 25, and 50  $\mu\text{g a.i./L}$ , the respective dry body weights for male mysids were 0.78, 0.82, 0.75, and 0.78 mg, while respective dry body weights for females were 0.93, 0.93, 0.93, and 0.81 mg. Statistically significant reduced dry body weights occurred in exposure concentrations to the test material of 25 and 50  $\mu\text{g a.i./L}$  for males and 50  $\mu\text{g a.i./L}$  for females.

"Based on the results of this study, the LOEC and NOEC of (S)-Methoprene technical for mysid survival, reproductive success and growth (total body length and dry weight) was determined. Dry body weight of male mysids was determined to be the most sensitive indicator of toxicity of (S)-Methoprene technical to mysids. The LOEC and NOEC, based on male dry body weight, was 25 and 14  $\mu\text{g a.i./L}$ , respectively. The Maximum-Acceptable-Toxicant Concentration (MATC) was calculated to be  $> 14$  and  $< 25 \mu\text{g a.i./L}$  (Geometric Mean, MATC = 19  $\mu\text{g a.i./L}$ ). These data provided a MATC which corroborated the conservatively estimated MATC (i.e., 24  $\mu\text{g a.i./L}$ ) determined during previously conducted life-cycle tests (SLI Report #92-11-4518)."

**DISCUSSION:** This study was conducted following acceptable procedures outlined in FIFRA Guideline 72-4, Subdivision E of the U.S. EPA Pesticide Assessment Guidelines (1982). This study determined the following values for (S)-methoprene technical to mysid shrimp: LOEC of 25  $\mu\text{g a.i./L}$ , NOEC of 14  $\mu\text{g a.i./L}$ , and MATC  $> 14$  and  $< 25 \mu\text{g a.i./L}$  (geometric mean MATC = 19  $\mu\text{g a.i./L}$ ). These values are based on the dry body weight for male mysids, which was determined to be the most sensitive performance criterion measured in these tests. The mortality data (presented as "Percent Survival") were reported to be significant only at the 98  $\mu\text{g a.i./L}$  level, and sublethal data at this level were not used in statistical calculations.

Although mortality was measured, no  $\text{LC}_{50}$  was calculated since 50% mortality was never achieved, nor did the data seem to follow a dose-response curve, i.e., percent survival was lower at the two lower treatment concentrations (78% for both) than at the next two higher treatment concentrations (82 and 83%) but lowest at the highest concentration of 98  $\mu\text{g a.i./L}$  (57%). The survival data shown in Table 1 are the actual percentages measured in each aquarium, with the mean given for the two aquaria per concentration. The reduction in survival does not follow a dose-response fashion, except that the greatest mortality occurs in the highest treatment concentration level. Although the Williams' Test showed no significant difference in survival between each of the treatments and the pooled controls (at  $\leq 50 \mu\text{g a.i./L}$ ), the use of only two data points (per treatment) does not give a standard deviation and is of questionable statistical validity.



The authors report no significant effect of the test material on reproductive success in mysids. However, the reproductive data shown in Table 1 is presented in a similar fashion to the survival data. When the number of reproducing females and the number of reproductive days are divided out, all of the reproductive data within an aquarium is reduced to a single number. Again, the use of only two values is of questionable statistical validity. The reviewer repeated the statistical analyses of the author regarding survival and reproduction and concurs with the author's conclusion.



TABLE 1. Summary of the first generation ( $F_0$ ) survival and reproductive success (offspring/female/reproductive day) during the 28-day life-cycle exposure of mysids (*Mysidopsis bahia*) to (S)-Methoprene Technical

Mean Measured Concentration $\mu\text{g a.i./L}$	Replicate	Percent Survival <sup>a</sup>	Reproductive Success <sup>a</sup>
Control	A	90	0.41
	B	90	0.79
	Mean	90	0.60
Solvent Control	A	90	0.33
	B	93	0.44
	Mean	92	0.39
Pooled Control <sup>b</sup>	Mean	91	0.50
7.2	A	73	0.42
	B	83	0.29
	Mean	78	0.36
14	A	73	0.44
	B	83	0.46
	Mean	78	0.45
25	A	87	0.49
	B	77	0.25
	Mean	82	0.37
50	A	83	0.18
	B	83	0.25
	Mean	83	0.22
98	A	60	0.083
	B	53	0.0094
	Mean	57 <sup>c</sup>	0.046 <sup>d</sup>

Data taken from Table 3, p. 34, MRID 44022101.

<sup>a</sup> Values presented have been rounded to two significant figures.

<sup>b</sup> Since control and solvent control data were not determined to be significantly different, all treatment data were compared to the pooled control data.

<sup>c</sup> Significantly different ( $p \leq 0.05$ ) from the pooled control (Williams' Test).

<sup>d</sup> Since organism survival was adversely affected, this treatment level was excluded from statistical analysis to determine treatment effects for body length, body weight, and reproductive success.



(A)



United States Environmental Protection Agency  
Office of Pesticide Programs (H7505C)  
Washington, DC 20460

## Application for Pesticide:

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

155977

## Section I

1. Company/Product Number 2724-448	2. EPA Product Manager Phil Hutton	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zoecon RF-330 ALTOSID Pellets	PM# 18	
5. Name and Address of Applicant (Include ZIP Code) Zoecon Corporation A Sandoz Company 12200 Denton Drive Dallas, TX 75234 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____ Product Name _____

## Section II

<input checked="" type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Removal of Fish Habitat

## Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit Package wgt. _____ No. per container _____	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package wgt. _____ No. per container _____	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container 25 lbs. to 100 lbs.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other (_____)			

## Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kelly J. Parker	Title Regulatory Specialist	Telephone No. (Include Area Code) 214/888-8726
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature 	3. Title Regulatory Specialist	
4. Typed Name Kelly J. Parker	5. Date 14 June 1993	



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**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

- **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.


**SECTION III (Packaging and Container Information)** - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- **1. Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- **2. Type of Retail Container** - Indicate type of container in which product will be marketed.
- **3. Location of Net Contents** - Specify the net contents of all retail containers for your product.
- **4. Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
- **5. Location of Use Directions** - Indicate the location of the use directions for your product.
- **6. Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point)** - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460		<input type="checkbox"/> Registration	OPP Identifier Number  <b>155977</b>
	Application for Pesticide:		<input checked="" type="checkbox"/> Amendment	
			<input type="checkbox"/> Other	

## Section I

1. Company/Product Number 2724-448	2. EPA Product Manager Phil Hutton	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zoecon RF-330 ALTOSID Pe Bellets	PM# 18	
5. Name and Address of Applicant (Include ZIP Code) Zoecon Corporation A Sandoz Company 12200 Denton Drive Dallas, TX 75234 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____ Product Name _____

## Section II

<input checked="" type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.


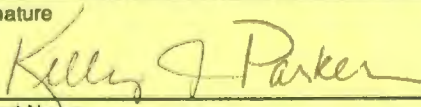
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Removal of Fish Habitat

## Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input checked="" type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted.					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container 25 lbs. to 100 lbs.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			
6. Manner In Which Label Is Affixed To Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other (_____)			

## Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Kelly J. Parker		Title Regulatory Specialist		Telephone No. (Include Area Code) 214/888-0826	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)  
2. Signature 		3. Title Regulatory Specialist			
4. Typed Name Kelly J. Parker		5. Date 14 June 1993			



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2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information)** - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point)** - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



[ ] indicates optional wording

# ZOECON RF-330 ALTOSID PELLETS

## MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

[Prevents Nuisance Midge Emergence]

### ACTIVE INGREDIENT:

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoate]..... 4.0%

INERT INGREDIENTS:..... 96.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WEIGHT:

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including Culex and Culiseta spp., as well as adults of the floodwater mosquitoes such as Aedes, Anopheles and Psorophora spp. from treated sites. ALTOSID Pellets also controls nuisance midge larvae.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID insect growth regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [or midges] which have reached the pupal or adult stage prior to treatment.

### APPLICATION SITES AND RATES:

MOSQUITO HABITAT	RATES (Lbs/Acre)
------------------	------------------

#### FLOODWATER SITES

Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
---	---------

Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
--	--------

#### PERMANENT WATER SITES

Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other other artificial water holding containers	2.5 - 5
---	---------

Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds	5 - 10
---	--------

MIDGE HABITAT	RATES (Lbs/Acre)
---------------	------------------

Midge larvae occur in natural and man-made aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds, and natural and man-made lakes. Apply pellets uniformly to the water surface. Repeat application as necessary.	5 - 10
---	--------

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Zoecon Corporation  
A Sandoz Company

12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-448  
0693-C

EPA Est. No.  
Made in USA



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[Prevents Nuisance Midge Emergence]

### ACTIVE INGREDIENT:

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11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoate).....

4.0%

INERT INGREDIENTS:..... 96.0%

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## CAUTION

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**NOTE:** This insect growth regulator has no effect on mosquitoes [or midges] which have reached the pupal or adult stage prior to treatment.

### APPLICATION SITES AND RATES:

MOSQUITO HABITAT	RATES (Lbs/Acre)
------------------	------------------

#### FLOODWATER SITES

Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
---	---------

Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
--	--------

#### PERMANENT WATER SITES

Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other other artificial water holding containers	2.5 - 5
---	---------

Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds	5 - 10
---	--------

MIDGE HABITAT	RATES (Lbs/Acre)
---------------	------------------

Midge larvae occur in natural and man-made aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds, and natural and man-made lakes. Apply pellets uniformly to the water surface. Repeat application as necessary.	5 - 10
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Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

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[Prevents Nuisance Midge Emergence]

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dodecadienoate].....

4.0%

INERT INGREDIENTS..... 96.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**NET WEIGHT:**

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Culex* and *Culiseta* spp., as well as adults of the floodwater mosquitoes such as *Aedes*, *Anopheles* and *Psorophora* spp. from treated sites. ALTOSID Pellets also controls nuisance midge larvae.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID insect growth regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [or midges] which have reached the pupal or adult stage prior to treatment.

### APPLICATION SITES AND RATES:

MOSQUITO HABITAT	RATES (Lbs/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other other artificial water holding containers	2.5 - 5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds	5 - 10
<b>MIDGE HABITAT</b>	
Midge larvae occur in natural and man-made aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds, and natural and man-made lakes. Apply pellets uniformly to the water surface. Repeat application as necessary.	5 - 10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

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dodecadienoate].....

4.0%

### INERT INGREDIENTS:

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**NOTE:** This insect growth regulator has no effect on mosquitoes [or midges] which have reached the pupal or adult stage prior to treatment.

### APPLICATION SITES AND RATES:

#### MOSQUITO HABITAT

#### RATES (Lbs/Acre)

##### FLOODWATER SITES

Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers 2.5 - 5

Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions 5 - 10

##### PERMANENT WATER SITES

Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other other artificial water holding containers 2.5 - 5

Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds 5 - 10

#### MIDGE HABITAT

#### RATES (Lbs/Acre)

Midge larvae occur in natural and man-made aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds, and natural and man-made lakes. Apply pellets uniformly to the water surface. Repeat application as necessary. 5 - 10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

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### APPLICATION SITES AND RATES:

MOSQUITO HABITAT	RATES (Lbs/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other other artificial water holding containers	2.5 - 5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds	5 - 10
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Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

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### APPLICATION SITES AND RATES:

MOSQUITO HABITAT	RATES (Lbs/Acre)
------------------	------------------

#### FLOODWATER SITES

Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
---	---------

Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
--	--------

#### PERMANENT WATER SITES

Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other other artificial water holding containers	2.5 - 5
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Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds	5 - 10
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MIDGE HABITAT	RATES (Lbs/Acre)
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**SANDOZ AGRO, INC.**

1300 EAST TOUCHY AVENUE, DES PLAINES, ILLINOIS 60018-3300

S **SANDOZ**

2724-375

2-11-95

BPPD

L. Wilson

NO.

**CORPORATE HEADQUARTERS**

TEL 708.699.1616

Registration Division (7505W)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460

February 14, 1995

To: Ms. Janet Andersen, Director, BPPD

Re: Methoprene Aquatic Hazard Label Statements - Submission of alternate wording for Altosid® products

Thank you once again for meeting with us yesterday relative to Sandoz priorities. It was a pleasure meeting you and I will look forward to working with you in the future. In following up with your request for suggestions as to possible label statements for outdoor-use methoprene products - please consider the following. Two statements related to the use of Altosid products in aquatic environments are in question:

## 1) For fish:

The statement "Do not apply to fish-bearing waters" was placed on Altosid labels at a time when there was insufficient data available to evaluate the chronic risk to fish. Data have now been submitted and reviewed which support that this statement can be removed.

## 2) For Aquatic invertebrates:

The statement "This product is toxic to aquatic invertebrates" was requested following the 1982 methoprene registration standard. After discussions relative to the fact that the levels of active ingredient released into the environment using these products were not high enough to significantly affect non-target species - the statement was not enforced. Concerns were raised recently due to the fact that methoprene does indeed affect aquatic invertebrates (namely mosquito larvae and - to some degree midge larvae) - a warning statement has again been requested. Rather than the general statement above, Sandoz is proposing a more specific and correct alternative.

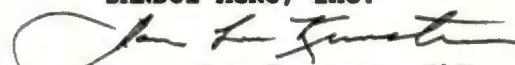
**ACTION:** To bring our Altosid labels up to date - Sandoz proposes the following label actions:

- 1) For Fish: remove current statement - no statement required
- 2) For Aquatic invertebrates: add the following statement to outdoor-use product labels:

"This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midges) larvae"

Since this issue is our number one IGR priority at this time - we would like to resolve it by March 17 if possible, and would appreciate your quick action on this proposal. If you have any additional questions on these matters - please feel free to contact me at (708) 390-3664.

SANDOZ AGRO, Inc.



James Lee Kunstman, PhD.  
Registration Manager

6/2/95 WKL



**SANDOZ AGRO, INC.**

1300 EAST TOUHY AVENUE, DES PLAINES, ILLINOIS 60018-3300

**SANDOZ**

RECD EPA/GPP/DPD2

'96 MAY 28 AIO :17

**CORPORATE HEADQUARTERS**

TEL. 847.699.1616

440221-00

Environmental Protection Agency  
Office of Pesticide Programs (H7505C)  
Document Processing Desk  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

May 23, 1996

Attn: Mr. Willie Nelson

Subject: Submission of S-Methoprene Reports in Support of Resolution of  
Aquatic Hazard Label Statements.

Products: Altosid Liquid Larvicide (A.L.L.) - EPA Reg. No. 2724-392 ✓  
A.L.L. Concentrate - EPA Reg. No. 2724-446  
Altosid Briquets - EPA Reg. No. 2724-375 ✓  
Altosid XR Briquets - EPA Reg. No. 2724-421 ✓  
Altosid Pellets - EPA Reg. No. 2724-448 ✓  
Altosid Granules - EPA Reg. No. 2724-ULR ✓

Please find enclosed 3 copies of the following reports in support of resolution of  
aquatic hazard label statements for the above referenced mosquito control  
products containing S-Methoprene:

1. (S)-Methoprene Technical - Chronic Toxicity to Mysids (*Mysidopsis bahia*)  
Under Flow-through Conditions. SLI Report #96-2-6378. Springborn  
Laboratories, Inc. April 2, 1996. *h*
2. An Assessment of Non-Target Effects of the Mosquito Larvicides, Bti and  
Methoprene, in Metropolitan Area Wetlands. A Report from the Scientific  
Peer Review Panel to the Metropolitan Mosquito Control District (MMCD).  
January, 1996. *164*
3. Methoprene (Altosid) Label Issues - Position Summary. Sandoz Agro, Inc.  
May, 1996.

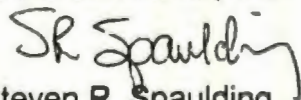
The Mysid Life-Cycle Toxicity Test was successfully completed after two previous studies were determined by EPA to be invalid due to poor population survival rates and poor reproduction success in the control groups. The Maximum-Acceptable-Toxicant Concentration (MATC) was calculated to be  $>14$  and  $<25\mu\text{g A.I./L}$ , which is similar to the values reported in the previous 2 invalid studies. This study has been repeated in response to your letter of July 20, 1994 in order to fulfill Guideline 72-4 requirements for an estuarine invertebrate chronic toxicity study.

The MMCD study evaluated potential effects of methoprene on non-target organisms after repeated use and failed to find any significant effects on birds, amphibians, zooplankton and most non-target insects.

The Methoprene Label Issues Position Summary provides rational for our request to: (1) remove the warning statement "Do not apply to fish-bearing waters" from all solid Altosid mosquito control products and (2) add the statement "This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae" to all Altosid mosquito control products.

We would like to request a followup meeting with the BPPD following review of the submitted information in order to reach final resolution of this issue. Please contact me at (847)390-3007 if you have any questions.

Yours Sincerely,  
SANDOZ AGRO, Inc.



Steven R. Spaulding  
Sr. Regulatory Specialist



TRANSMITTAL DOCUMENT

SUBMITTED BY

Sandoz Agro Inc.  
1300 E. Touhy Ave.  
Des Plaines, Illinois 60018

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Submission of reports in support of resolution of label issues for Altosid mosquito control products.

TRANSMITTAL DATE

May 23, 1996

LIST OF SUBMITTED STUDIES

Volume 1 (S)-Methoprene Technical - Chronic Toxicity to Mysids (*Mysidopsis bahia*) Under Flow-through Conditions. SLI Report #96-2-6378. Springborn Laboratories, Inc. April 1996.

MRID No. 44022101

Volume 2 An Assessment of Non-Target Effects of the Mosquito Larvicides, Bti and Methoprene, in Metropolitan Area Wetlands. A Report from the Scientific Peer Review Panel to the Metropolitan Mosquito Control District. January, 1996.

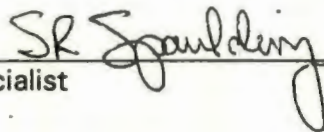
MRID No. 44022102

Volume 3 Methoprene (Altosid) Label Issues - Position Summary. Sandoz Agro, Inc. May, 1996.

MRID No. 44022103

COMPANY OFFICIAL:

Steven R. Spaulding  
Senior Registration Specialist



COMPANY NAME:

SANDOZ AGRO, INC.

COMPANY CONTACT:

Steven R. Spaulding (847) 390-3007

RECD EPA/GPP/DPD2

 **SANDOZ**

96 MAY 28 AIO :17

440221-00

**CORPORATE HEADQUARTERS**

TEL. 847.699.1616

May 23, 1996

Environmental Protection Agency  
Office of Pesticide Programs (H7505C)  
Document Processing Desk  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Attn: Mr. Willie Nelson

Subject: Submission of S-Methoprene Reports in Support of Resolution of  
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Altosid Briquets - EPA Reg. No. 2724-375 ✓  
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Altosid Pellets - EPA Reg. No. 2724-448 ✓  
Altosid Granules - EPA Reg. No. 2724-ULR ✓

Please find enclosed 3 copies of the following reports in support of resolution of aquatic hazard label statements for the above referenced mosquito control products containing S-Methoprene:

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2. *not required* An Assessment of Non-Target Effects of the Mosquito Larvicides, Bti and Methoprene, in Metropolitan Area Wetlands. A Report from the Scientific Peer Review Panel to the Metropolitan Mosquito Control District (MMCD). January, 1996.
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REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

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May 23, 1996

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MRID No. 44022103

COMPANY OFFICIAL:

Steven R. Spaulding  
Senior Registration Specialist

*SR Spaulding*

COMPANY NAME:

SANDOZ AGRO, INC.

COMPANY CONTACT:

Steven R. Spaulding (847) 390-3007

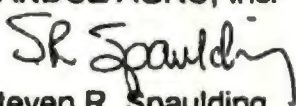
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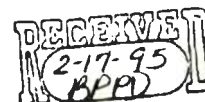
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Yours Sincerely,  
SANDOZ AGRO, Inc.

  
Steven R. Spaulding  
Sr. Regulatory Specialist





*W NELSON*

*NO!*

**CORPORATE HEADQUARTERS**

TEL 708 699 1616

Registration Division (7505W)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460

February 14, 1995

To: Ms. Janet Andersen, Director, BPPD

Re: Methoprene Aquatic Hazard Label Statements - Submission of alternate wording for Altosid® products

Thank you once again for meeting with us yesterday relative to Sandoz priorities. It was a pleasure meeting you and I will look forward to working with you in the future. In following up with your request for suggestions as to possible label statements for outdoor-use methoprene products - please consider the following. Two statements related to the use of Altosid products in aquatic environments are in question:

1) For fish:

The statement "Do not apply to fish-bearing waters" was placed on Altosid labels at a time when there was insufficient data available to evaluate the chronic risk to fish. Data have now been submitted and reviewed which support that this statement can be removed.

2) For Aquatic invertebrates:

The statement "This product is toxic to aquatic invertebrates" was requested following the 1982 methoprene registration standard. After discussions relative to the fact that the levels of active ingredient released into the environment using these products were not high enough to significantly affect non-target species - the statement was not enforced. Concerns were raised recently due to the fact that methoprene does indeed affect aquatic invertebrates (namely mosquito larvae and - to some degree midge larvae) - a warning statement has again been requested. Rather than the general statement above, Sandoz is proposing a more specific and correct alternative.

**ACTION:** To bring our Altosid labels up to date - Sandoz proposes the following label actions:

- 1) For Fish: remove current statement - no statement required
- 2) For Aquatic invertebrates: add the following statement to outdoor-use product labels:

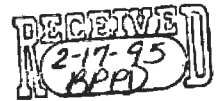
"This product is toxic to aquatic dipteran (mosquitoes) and Chironomid (midges) larvae"

Since this issue is our number one IGR priority at this time - we would like to resolve it by March 17 if possible, and would appreciate your quick action on this proposal. If you have any additional questions on these matters - please feel free to contact me at (708) 390-3664.

SANDOZ AGRO, Inc.

James Lee Kunstman, PhD.  
Registration Manager

*6/2/95 WLN*



*W NELSON*

*NO!*

**CORPORATE HEADQUARTERS**

TEL 708.699.1616

Registration Division (7505W)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460

February 14, 1995

To: Ms. Janet Andersen, Director, BPPD

Re: Methoprene Aquatic Hazard Label Statements - Submission of alternate wording for Altosid® products

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SANDOZ AGRO, Inc.

*James Lee Kunstman*  
James Lee Kunstman, PhD.  
Registration Manager

6/2/95 WKN





W NELSON

NO!

**CORPORATE HEADQUARTERS**

TEL 708.699.1616

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Office of Pesticide Programs  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
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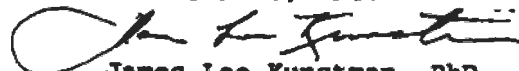
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SANDOZ AGRO, Inc.

  
James Lee Kunstman, PhD.  
Registration Manager

6/2/95 WNN

DP BARCODE: D206771

CASE: 010616  
SUBMISSION: S472104

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 08/22/94  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION  
RANKING : 10 POINTS ()  
CHEMICALS: 105401 Methoprene

ACTION: 675

RESUBMISSION

2724-448  
4.0000%

ID#: 002724-00448 ZOECON RF-330 ALTOSID PELLETS

COMPANY: 002724 SANDOZ ANIMAL HEALTH

PRODUCT MANAGER: 18 PHILLIP HUTTON

703-305-7690

ROOM: CM2

213

PM TEAM REVIEWER: WILLIE NELSON

703-305-6601

ROOM: CM2

209

RECEIVED DATE: 08/09/94

DUE OUT DATE: 02/05/95

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 206771

EXPEDITE: Y

DATE SENT: 08/22/94

DATE RET.: / /

CHEMICAL: 105401 Methoprene

DP TYPE: 001 Submission Related Data Package

CSF: N

LABEL: N

ASSIGNED TO

DATE IN

DATE OUT

ADMIN DUE DATE: 11/20/94

DIV : HED

8/23/94

/ /

NEGOT DATE: / /

BRAN: SAB

/ /

/ /

PROJ DATE: / /

SECT: BS

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/ /

REVR :

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CONTR:

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\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Roy/John- please review these data submitted in support of  
the reregistration of Methoprene.

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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mpid# 433338-01

Acutis

oral

-02 Derm

-03 ~~oral~~

-04 Eye In

-05 Derm In

-05 Derm - Ins



## EXPLANATIONARY LABELING

2724- yu±

## Acknowledge

58



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 12 2005

Ms. Nancy Huebl  
Regulatory Specialist  
Wellmark International  
1501 East Woodfield Road, Suite 200 West  
Schaumburg, Illinois 60173

**Subject: Zoecon RF-330 Altosid Pellets; EPA No: 2724-448**  
**Notification of alternate brand name**  
**Notification to add directions for use claims for water soluble**  
**packaging and corresponding amendment to Storage and Disposal**  
**section; Your Application Dated March 18, 2005**

Dear Ms. Huebl:

Your notification for an alternate brand name, Zoecon Altosid Pellets WSP, and to add Directions for Use/claims for water soluble packing for the above product are acceptable. However, for your future reference, changes to Storage and Disposal statements are to be brought in as part of a label amendment, for the following reasons:

According to PR Notice 2000-5, Guidance for Mandatory and Advisory Labeling Statements, changes in advisory labeling statements can only be made by submitting an amendment.

The first paragraph of this PR Notice includes: "For purposes of this notice, the term "use" includes storage, transportation, handling, pre-application activities, mixing and loading, worker notification and worker protection, application, post-application activities and disposal. ... Finally, registrants may no longer add or change advisory labeling statements to existing products by notification as previously permitted by PR Notices 95-2 and 98-10."

As required under 40 CFR, Section 152.44, amendments to revise the labeling must be approved by the Agency before the above product, as modified, may legally be distributed or sold.

CONCURRENCES							
SYMBOL	2511C	2511C	2511C				
SURNAME	Pollaro	Petersen	Pull				
DATE	12/8/05	12/8/05	12/12/05				



If you have any questions or comments please contact Linda Hollis at 703/308-8733, or email her at [hollis.linda@epa.gov](mailto:hollis.linda@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Sheryl K. Reilly". The signature is fluid and cursive, with the first name "Sheryl" being more prominent.

Sheryl K. Reilly, Ph.D., Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511C)

Enclosure



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-448	2. EPA Product Manager S. Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Zoecon RF-330 Altosid Pellets	PM # Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and section II.)

Notification per PRN 94-8 to add Directions for Use/claims for water soluble packaging, notification of alternate brand name: Zoecon Altosid Pellets WSP. This notification is consistent with the provisions of PR Notice 94-8 & 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 94-8 & 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

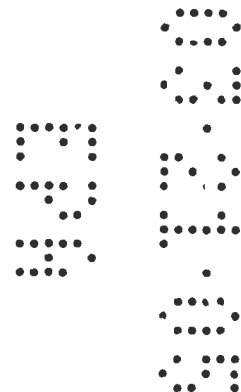
## Section - III

1. Material This Product Will be Packaged In:			2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) foil lined plastic outer pouch	
* Certification must be submitted	If "Yes" Unit Packaging wgt. 7 gm minimum No. per container 50	If "Yes" Unit Packaging wgt. 7 gm minimum No. per container 50		
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 50 - 7 gram (min) WSP	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Regulatory Specialist	Telephone No. (Include Area Code) (847) 330-5376
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature <i>Nancy Huebl</i>	3. Title Regulatory Specialist	
4. Typed Name Nancy Huebl	5. Date 18-Mar-05	





March 18, 2005

Document Processing Desk (NOTIF)  
Office of Pesticide Programs 7504C  
U.S. Environmental Protection Agency  
Crystal Mall 2 Room 266A  
1801 South Bell Street  
Arlington, Virginia 22202

ATTENTION: S. Reilly

SUBJECT: NOTIFICATION OF LABEL REVISION PER PRNS 94-8 & 98-10  
ZOËCON® RF-330 ALTOSID® PELLETS/EPA REG. NO. 2724-448

Dear Ms. Reilly:

Enclosed is completed EPA Form 8570-1 and one copy of revised labeling (red is new text) for the above product. The revision involves adding a WSP (water soluble packaging) sublabel to this product registration. Pages 1-5 represent the original EPA approved label, pages 6-9 represent the label for the WSP (Sublabel B). The red highlighted text in Sublabel B is the specific text related to the WSP addition (no additional sites or pest species). The remainder of unhighlighted text in Sublabel B is duplicate text from Sublabel A. This notification to add WSP meets all the criteria stated in PRN 94-8. Specifically, these include:

PRN 94-8, §II

1. Any WSP file or ink proposed for use must have been previously determined by EPA to be acceptable for such use. Each constituent component of a WSP file must be individually approved for use and, if the product is to be registered for food use, have the appropriate tolerance exemption under 40 CFR 180.1001 (c)(d)(e). The registrant should provide the trade name and chemical name and/or trade name and supplier's name/address for each proposed WSP film.

**Enclosed is a Product Information bulletin for the water-soluble film that will be used for Wellmark's WSP. The trade name of the film and supplier's name and address are shown. Although the film is exempt from tolerance, the label does not include any food site applications. Because the individual WSP unit is small and will be integrally sealed in an outer container that bears appropriate labeling, no ink data are included.**

2. Film/ink should not react with the ingredients of the product. **Film does not react with Zoëcon RF-330 Altosid Pellets.**

Page 2

March 18, 2005

Document Processing Desk (NOTIF)  
Office of Pesticide Programs 7504C  
U.S. Environmental Protection Agency

03.21.05

EPA

ATTENTION: S. Reilly

SUBJECT: NOTIFICATION OF LABEL REVISION PER PRNS 94-8 & 98-10  
ZOËCON® RF-330 ALTOSID® PELLETS/EPA REG. NO. 2724-448

3. Directions for use on the product label submitted to EPA must provide mixing directions both for WSP and other forms of packaging approved for that product. The WSP directions should result in a mixed solution which will be applied at the same dosage, concentration and frequency as approved for other types of packaging for that product. **The dosage/concentration/frequency of the WSP is equivalent to that of the non-WSP product.**

4. Labeling of an individual WSP unit is optional if the WSP is integrally sealed in an outer container that bears appropriate labeling. **50 small WSP's will be sealed in a ziplock outer foil bag. Label directions state "Once outer foil bag containing water soluble pouches is opened, use pouches within one day."**

This notification (per PRN 98-10) also serves to notify you of alternate brand name (for WSP): ZOËCON® ALTOSID® PELLETS WSP.

If you have any questions, please, call me directly at 847/330-5376 or contact me via email. Thank you for your assistance in this matter.

Yours sincerely,  
WELLMARK INTERNATIONAL

*Nancy Huebl*

Nancy Huebl  
Regulatory Specialist  
[nancy.huebl@wellmarkint.com](mailto:nancy.huebl@wellmarkint.com)

enclosure

cc: C. Elmi/J. Richardson





Label Review Sheet

**FILENAME:** g:\regulatory\LABELS\  
02724448\epa notif wsp 305

**COVERSHEET  
UPDATE:**

March 2005

**PRODUCT:** ZOECON RF-330  
ALTOSID PELLETS

**EPA REG. NO.:**

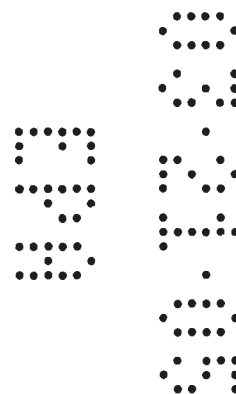
2724-448

**APPROVED:** Notification submitted 3/05

**SUPERSEDES:**

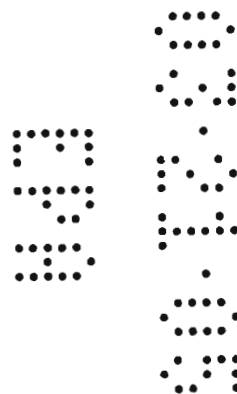
**OVERVIEW:** Per PRN 94-8 & 98-10 add WSP sublabel (B) (pages 6-9) and alternate brand name for sublabel B – Zoëcon® Altosid® Pellets WSP

Page #	Description of Major Changes
6	Alternate brand name: Zoëcon® Altosid® Pellets WSP
7	Marketing claims for WSP – Ideal when treating hard-to-reach stormwater sites Ready-to-use water soluble pouches A single WSP covers up to 135 ft² of water surface area Net Weight: 50.7 gram WSP
8	Differentiated Directions for Use as WSP
9	Directions for Use: Added general directions for WSP as well as Application sites and Rate Storage and Disposal: Added header "Storage" Added Container Disposal for WSP (per label review manual)





MASTER LABEL



**SUBLABEL A**

[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence  
(including those which may transmit West Nile virus)  
[Prevents Nuisance Midge [Filter Fly] Emergence]  
[Controls waste water nuisance pests][filter flies]

**ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #65733-16-6) .....4.25%

**OTHER INGREDIENTS:**.....95.75%

Total .....100.00%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See back panel [below] for additional Precautionary Statements

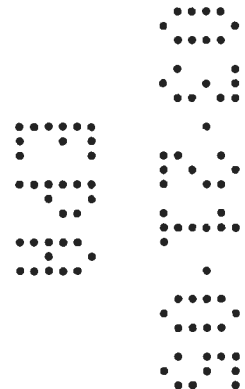
EPA Reg. No. 2724-448

EPA Est. No.

Best if used by:

**Lot No.**

**NET WEIGHT: 8 and 22 lbs.**





## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

FIRST AID	
Call a poison control center or doctor for treatment advice.	
If in eyes	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li></ul>
If on skin or clothing	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li></ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-[phone number] for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

**ENVIRONMENTAL HAZARDS:** Do not contaminate water when disposing of rinsate or equipment washwaters.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID®, an Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquillettidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes*, *Ochlerotatus*, and *Psorophora* spp. from treated sites. ALTOSID Pellets also control nuisance midge larvae.

**[INTRODUCTION:** ALTOSID® Pellets are a unique product that control filter flies (*Psychoda* spp.), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water facilities. ALTOSID Pellets contain an Insect Growth Regulator (IGR) that is effective on the developing stages of insect pests. ALTOSID Pellets do not kill adults but affects the larval stages as they grow and develop. ALTOSID Pellets stop the formation of pupae of insect pests, thereby eliminating adult populations. ALTOSID Pellets stop the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.]

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Continue treatment through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [midges][filter flies] which have reached the pupal or adult stage prior to treatment.

### APPLICATION SITES AND RATES:

Use lower application rates when water is shallow, vegetation and/or pollution are minimal, and insect populations are low. Use higher rates when water is deep (>2 ft), vegetation, pollution, and/or organic debris or water flow are high, and insect populations are high. [In instances of high organic debris and water flow, residual activity may be diminished.]

#### MOSQUITO HABITAT

#### RATES (Lb/Acre)

##### FLOODWATER SITES

Pastures, meadows, rice fields, freshwater swamps and marshes, salt and tidal marshes, cattail marshes, woodland pools, floodplains, tires, other artificial water-holding containers

2.5-5

Dredging spoil sites, waste treatment and settling ponds, ditches and other manmade depressions

5-10

##### PERMANENT WATER SITES

Ornamental ponds and fountains, fish ponds, cattail marshes, water hyacinth beds, flooded crypts, transformer vaults, abandoned swimming pools, construction and other manmade depressions, treeholes, other artificial water-holding containers

2.5-5

Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds, vegetation-choked phosphate pits

5-10

#### MIDGE HABITAT

#### RATES (Lb/Acre)

Midge larvae occur in natural and manmade aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds, and natural and manmade lakes. Apply pellets uniformly to the water surface. Repeat application as necessary.

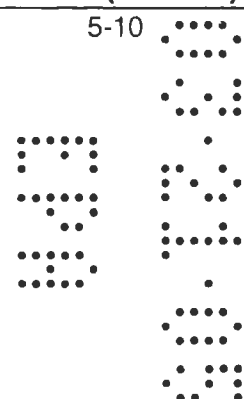
5-10

#### FILTER FLY HABITAT

#### RATES (Lb/Acre)

Filter flies and midges are waste water treatment pests inhabiting sludge drying beds, clarifiers, holding tanks or ponds, sewage lagoons, evisceration ponds, paper or food waste ponds, stagnant or standing water, or other areas of waste water treatment facilities where midges, filter flies, and other nuisance aquatic insect pests are a problem.

5-10





## APPLICATION METHODS

**Mosquitoes/Midges:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10 lb/acre may be used to apply ALTOSID Pellets. The pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. Apply ALTOSID Pellets to artificial containers such as tires and catch basins, etc.

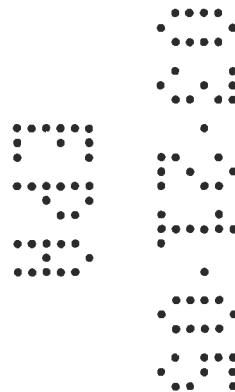
**[Waste Water Nuisance Pests:** For applications to solid waste, including sludge and retention ponds, use the initial high rate of 10 lb/acre. Immediately following filling of the drying beds, apply the product uniformly to the surface of the bed. Application of ALTOSID Pellets to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

For applications in aquatic habitats, including waste water treatment facilities, evisceration ponds, sewage lagoons, manure runoff areas, retention ponds, and holding tanks, apply ALTOSID Pellets as uniformly as possible over the entire surface. In situations where the ponds are large, applications made around the perimeter of the ponds can be helpful in reducing pests. In these situations, apply up to a 20 foot band out from the bank around the pond perimeter.

Apply ALTOSID Pellets using suitable application equipment, such as, hand or motorized spreaders, backpack blowers, or aircraft (rotary or fixed wing). Even coverage over the surface of the area to be treated is critical for optimum performance.

**What to Expect in Waste Water Facilities:** Following initial applications of ALTOSID Pellets, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be noticeable within a 2 week period following the application. Due to varying conditions or heavy infestations, the period to expect control may be longer. Since the mode of action of ALTOSID Pellets is to prevent adult emergence, existing adults and pupae present at the time of initial application will complete their life cycle.]

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. Store closed containers of ALTOSID Pellets in a cool dry place. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



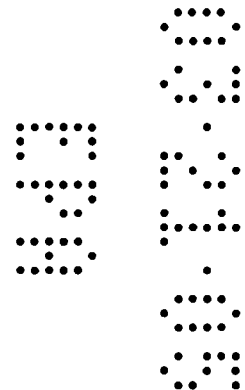
**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information or in case of an emergency, call [phone number] or visit our Web site [URL].

ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are registered trademarks of Wellmark International.

Wellmark International  
Schaumburg IL 60173

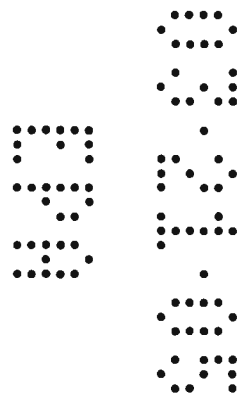
Made in USA





## SUBLABEL B

For alternate brand name:  
ZOËCON® ALTOSID® PELLETS WSP



[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence  
(including those which may transmit West Nile virus)

Ideal when treating hard-to-reach stormwater sites  
Ready-to-use water soluble pouches  
A single WSP covers up to 135 ft<sup>2</sup> of water surface area

**ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #65733-16-6) .....4.25%

**OTHER INGREDIENTS:** .....95.75%

Total .....100.00%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See back panel [below] for additional Precautionary Statements

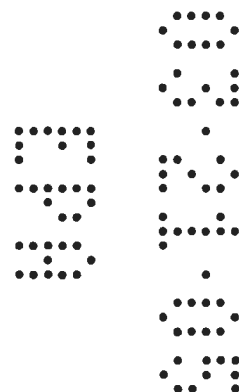
EPA Reg. No. 2724-448

EPA Est. No.

Best if used by:

**Lot No.**

NET WEIGHT: 50/7 gram water soluble pouches (.77 lb)





## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

FIRST AID	
Call a poison control center or doctor for treatment advice.	
If in eyes	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li></ul>
If on skin or clothing	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li></ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-[phone number] for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

**ENVIRONMENTAL HAZARDS:** Do not contaminate water when disposing of rinsate or equipment washwaters.

**(WSP) DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID®, an Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquillettidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes*, *Ochlerotatus*, and *Psorophora* spp. from treated sites.

**[INTRODUCTION:** ALTOSID Pellets contain an Insect Growth Regulator (IGR) that is effective on the developing stages of insect pests. ALTOSID Pellets do not kill adults but affects the larval stages as they grow and develop. ALTOSID Pellets stop the formation of pupae of insect pests, thereby eliminating adult populations. ALTOSID Pellets stop the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.]

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Continue treatment through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

ALTOSID Pellets WSP are convenient ready-to-use pouches for treating mosquito breeding sites. The pouches are water-sensitive and when in contact with water, the pouches dissolve, releasing the pellets. Use care when handling unused pouches so that moisture does not collect on the pouches. Keep pouches sealed in the original package until ready for use. Once outer foil bag containing water soluble pouches is opened, use pouches within one day.

#### APPLICATION SITES:

Altosid Pellets WSP are effective against *Anopheles*, *Culex*, *Culiseta*, *Aedes*, *Ochlerotatus*, *Coquillettidia*, *Mansonia* and *Psorophora* mosquito species. Use pouches to treat small bodies of water such as: catch basins, storm drains, roadside ditches, tree holes, flooded crypts, transformer pits, fish ponds, woodland pools, fountains, septic tanks, ornamental ponds, manmade depressions, animal watering troughs, ditches, and other natural or artificial water-holding containers.

#### APPLICATION RATE:

Place one pouch into each catch basin. For other mosquito breeding sites, one pouch will treat up to 135 ft<sup>2</sup> of surface area. Altosid Pellets WSP will provide up to 30 days control of emerging adult mosquitoes.

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal.

**Storage:** Store closed containers of ALTOSID Pellets in a cool, dry place. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** **Outer Foil Packets of Water Soluble Pouches:** Dispose of empty outer foil bag in the trash.

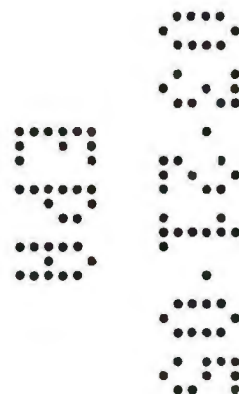
**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, expressed or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information or in case of an emergency, call [phone number] or visit our Web site [URL].

ALTOSID® and ZOËCON® are registered trademarks of Wellmark International.

Wellmark International  
Schaumburg IL 60173

Made in USA







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

*Gasket*

July 19, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-346377  
EPA File Symbol or Registration Number: 2724-448  
Product Name: ZOECON RF-330 ALTOSID PELLETS  
EPA Receipt Date: 01-Jul-2004  
EPA Company Number: 2724  
Company Name: WELLMARK INTERNATIONAL

STEVE SPAULDING  
WELLMARK INTERNATIONAL  
1100 EAST WOODFIELD ROAD, SUITE 500  
SCHAUMBURG, IL 60173

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B68

AMENDMENT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;

Please remit payment in the amount of: \$ 4,000 to:

By USPS:  
USEPA Washington Finance Center  
Pesticide Registration Service Fee  
PO Box 360277  
Pittsburgh, PA 15251

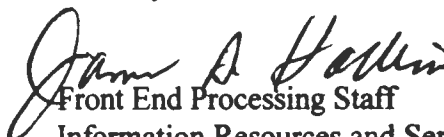
By Courier:  
U.S. EPA Washington Finance Center  
Pesticide Registration Service Fee  
C/O Mellon Client Service Center  
500 Ross Street, Room 670  
Box 360277  
Pittsburgh, PA 15251-6277  
Attn: EPA Module Supervisor  
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at [www.epa.gov/pesticides/fees](http://www.epa.gov/pesticides/fees).

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-8260.

Sincerely,



Front End Processing Staff  
Information Resources and Services Division



# Fee for Service

This package includes the following

☒ New FFS Action

☒ Amendment

☐ Waiver Request

☒ Voluntary Payment Request

for Division

☐ RD

☐ AD

☒ BPPD

Receipt Nos. S-

763148

Product/Risk Manager:

91

EPA File Symbol/Reg. No.

2724-448

Pin-Punch Date:

7-1-04

☐ This item is NOT subject to FFS action.

Action Code:

B68

Amount Due: \$

4,000

Voluntary Payment Reduction Amount:

☐ 0%

☐ 40%

☐ 80%

☐ 10%

☐ 50%

☐ 90%

☐ 20%

☐ 60%

☐ 100%

☐ 25%

☐ 70%

☐ Other

☐ 30%

☐ 75%

\_\_\_\_%

Original Decision #:

D-

Reviewer:

S. Reilly

Date:

7/16/04

Remarks:

*Jim note*  
This is not a vol pay -

This is a new, non-FT amendment  
(with data) S. Reilly

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Nancy Huebl  
Wellmark International  
1501 E. Woodfield Rd., Suite 200W  
Schaumburg, IL 60173

APR 11 2005

744266 | 300  
MD | 17

RE: Zoecon RF-330 Altosid Pellets  
EPA Registration Number: 2724-448  
Label Amendment to update First Aid statement  
Application dated: 15 August 2003

Dear Ms. Huebl:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), as amended, is acceptable provided that you:

1. Submit and/ or cite all data required for registration/ re-registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit five (5) copies of your final printed labeling before you release the product for your shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass, metal containers, large bags, or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have questions, please contact Mari Duggard, at 703-308-0028, or by e-mail at [duggard.mari@epa.gov](mailto:duggard.mari@epa.gov).

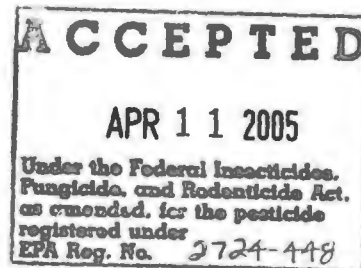
Sincerely,

*Sheryl K. Reilly*

Sheryl K. Reilly, Ph.D., Chief  
Biochemical Pesticide Branch  
Biopesticides and Pollution  
Prevention Division (7511C)

Enclosures:		CONCURRENCES					
SYMBOL	7511C	Copy of stamped Accepted Label					
SURNAME	DUGGARD	7511C					
DATE	4-1-05						





[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence  
(including those which may transmit West Nile virus)  
[Prevents Nuisance Midge [Filter Fly] Emergence]  
[Controls waste water nuisance pests][filter flies]

**ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #65733-16-6)..... 4.25%

**OTHER INGREDIENTS:**..... 95.75%

Total 100.00%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See back panel [below] for additional Precautionary Statements

EPA Reg. No. 2724-448

EPA Est. No.

Best if used by:

Lot No.

NET WEIGHT: 8 and 22 lbs.

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**CAUTION**

Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

FIRST AID	
Call a poison control center or doctor for treatment advice.	
If in eyes	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li></ul>
If on skin or clothing	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li></ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-[phone number] for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

**ENVIRONMENTAL HAZARDS:** Do not contaminate water when disposing of rinsate or equipment washwaters.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID®, an Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquillettidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes*, *Ochlerotatus*, and *Psorophora* spp. from treated sites. ALTOSID Pellets also control nuisance midge larvae.

**[INTRODUCTION:** ALTOSID® Pellets are a unique product that control filter flies (*Psychoda* spp.), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water facilities. ALTOSID Pellets contain an Insect Growth Regulator (IGR) that is effective on the developing stages of insect pests. ALTOSID Pellets do not kill adults but affects the larval stages as they grow and develop. ALTOSID Pellets stop the formation of pupae of insect pests, thereby eliminating adult populations. ALTOSID Pellets stop the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.]

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Continue treatment through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.



**NOTE:** This insect growth regulator has no effect on mosquitoes [midges][filter flies] which have reached the pupal or adult stage prior to treatment.

#### **APPLICATION SITES AND RATES:**

Use lower application rates when water is shallow, vegetation and/or pollution are minimal, and insect populations are low. Use higher rates when water is deep (>2 ft), vegetation, pollution, and/or organic debris or water flow are high, and insect populations are high. [In instances of high organic debris and water flow, residual activity may be diminished.]

<b>MOSQUITO HABITAT</b>	<b>RATES (Lb/Acre)</b>
<b><u>FLOODWATER SITES</u></b>	
Pastures, meadows, rice fields, freshwater swamps and marshes, salt and tidal marshes, cattail marshes, woodland pools, floodplains, tires, other artificial water-holding containers	2.5-5
Dredging spoil sites, waste treatment and settling ponds, ditches and other manmade depressions	5-10
<b><u>PERMANENT WATER SITES</u></b>	
Ornamental ponds and fountains, fish ponds, cattail marshes, water hyacinth beds, flooded crypts, transformer vaults, abandoned swimming pools, construction and other manmade depressions, treeholes, other artificial water-holding containers	2.5-5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds, vegetation-choked phosphate pits	5-10
<b><u>MIDGE HABITAT</u></b>	<b>RATES (Lb/Acre)</b>
Midge larvae occur in natural and manmade aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds, and natural and manmade lakes. Apply pellets uniformly to the water surface. Repeat application as necessary.	5-10
<b><u>FILTER FLY HABITAT</u></b>	<b>RATES (Lb/Acre)</b>
Filter flies and midges are waste water treatment pests inhabiting sludge drying beds, clarifiers, holding tanks or ponds, sewage lagoons, evisceration ponds, paper or food waste ponds, stagnant or standing water, or other areas of waste water treatment facilities where midges, filter flies, and other nuisance aquatic insect pests are a problem.	5-10

## APPLICATION METHODS

**Mosquitoes/Midges:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10 lb/acre may be used to apply ALTOSID Pellets. The pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. Apply ALTOSID Pellets to artificial containers such as tires and catch basins, etc.

**[Waste Water Nuisance Pests:** For applications to solid waste, including sludge and retention ponds, use the initial high rate of 10 lb/acre. Immediately following filling of the drying beds, apply the product uniformly to the surface of the bed. Application of ALTOSID Pellets to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.]

For applications in aquatic habitats, including waste water treatment facilities, evisceration ponds, sewage lagoons, manure runoff areas, retention ponds, and holding tanks, apply ALTOSID Pellets as uniformly as possible over the entire surface. In situations where the ponds are large, applications made around the perimeter of the ponds can be helpful in reducing pests. In these situations, apply up to a 20 foot band out from the bank around the pond perimeter.

Apply ALTOSID Pellets using suitable application equipment, such as, hand or motorized spreaders, backpack blowers, or aircraft (rotary or fixed wing). Even coverage over the surface of the area to be treated is critical for optimum performance.

**What to Expect in Waste Water Facilities:** Following initial applications of ALTOSID Pellets, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be noticeable within a 2 week period following the application. Due to varying conditions or heavy infestations, the period to expect control may be longer. Since the mode of action of ALTOSID Pellets is to prevent adult emergence, existing adults and pupae present at the time of initial application will complete their life cycle.]

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. Store closed containers of ALTOSID Pellets in a cool dry place. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information or in case of an emergency, call [phone number] or visit our Web site [URL].

ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are registered trademarks of Wellmark International.

Wellmark International  
Schaumburg IL 60173

Made in USA



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-448	2. EPA Product Manager S. Reilly	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Zoecon RF-330 Altosid Pellets	PM # Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1100 East Woodfield Road, Suite 500 Schaumburg, Illinois 60173  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and section II.)

Per J. Downing (8/11) phone call request (result of SLITS inquiry), amend label to add Precautionary Statements and First Aid with exact text per PRN 2001-1, revise the Environmental Hazards statements and modify Directions for Use per PRN 2000-5

## Section - III

1. Material This Product Will be Packaged In:						2. Type of Container	
Child-Resistant Packaging  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____			
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Unit Packaging wgt.	Unit	No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 8 and 22 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product			
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Regulatory Specialist	Telephone No. (Include Area Code) 847.330.5376
Certification  I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received  (Stamped)
2. Signature <i>Nancy Huebl</i>	3. Title Regulatory Specialist	
4. Typed Name Nancy Huebl	5. Date August 15, 2003	



Wellmark International  
1100 East Woodlawn Road, Suite 500  
Schaumburg, Ill. 60173  
647 330 5300

# Wellmark

August 15, 2003

Document Processing Desk (AMEND)  
Office of Pesticide Programs 7504C  
U.S. Environmental Protection Agency  
Room 266A Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202

ATTENTION: Sheryl Reilly, Biopesticides

SUBJECT: LABEL AMENDMENT FOR:  
ZOËCON® RF-292 BRIQUET/EPA REG. NO. 2724-421  
ZOËCON® RF-330 ALTOSID® PELLETS/EPA REG. NO. 2724-448  
ZOËCON® ALTOSID® BRIQUETS/EPA REG. NO. 2724-375

Dear Ms. Reilly:

Enclosed for each of the above registrations is a completed EPA Form 8570-1 and 5 copies of revised labeling. I've included one highlighted copy (red is new text; blue [strikeout] is deleted text) for convenience in reviewing noted changes. We are requesting an expedited review of these amendments because of the upcoming October 1 deadline for First Aid (PRN 2001-1) compliance. These are important mosquito control products especially with the West Nile virus threat, and if not approved by the October 1 deadline could result in production delays. An amendment was not submitted earlier because the EPA approved labels contained no Precautionary Statements (no First Aid). Per an August 11 telephone conversation with Jim Downing, a SLITS inquiry was recently submitted asking why the ZOËCON® RF-330 ALTOSID® PELLETS (2724-448) did not contain any Precautionary Statements. Upon review of the registration jacket, Mr. Downing called to advise Wellmark that the supporting tox data (reregistration) required label text reflecting a Tox III category for Acute Dermal and Eye Irritation. We are also submitting two similar solid mosquito formulation labels as well. In addition to these changes, we are revising the Environmental Hazards based upon a conversation between Jim Downing and Steve Spaulding. Text required due to a data gap (Estuarine Invertebrate Life Cycle) was deleted because study was reviewed/approved.

Minor mandatory/advisory revisions were made to the Directions for Use, as well, animal watering troughs were added as a site on the two briquet formulations (2724-375 and 2724-421). In previous communication with BPPD and state regulatory officials regarding a similar solid mosquito formulation (2724-451 - ALTOSID® 9010 GR), an interpretation was made to allow this specific use since it was included in a general way under "other artificial water-holding containers". We are also revising the application timing and rates directions on the ALTOSID Briquets (2724-375) to be consistent with the directions for the ZOËCON® RF-292 Briquet (2724-421) for enhanced end-user understanding.

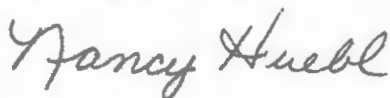
August 15, 2003

Document Processing Desk (AMEND)  
Office of Pesticide Programs 7504C  
U.S. Environmental Protection Agency  
Room 266A Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202

ATTENTION: Sheryl Reilly, Biopesticides

If you have any questions, please, call me directly at 847-330-5376 or contact me via email  
( [nancy.huebl@wellmarkint.com](mailto:nancy.huebl@wellmarkint.com) ). Thank you for your assistance in this matter.

Yours sincerely,  
WELLMARK INTERNATIONAL



Nancy Huebl  
Regulatory Specialist

enclosure

cc: S. Spaulding/C. Elmi/J. Richardson





"Huebl, Nancy"  
<Nancy.Huebl@wellmarkint.com>

11/12/04 11:42 AM

To: Mari Duggard/DC/USEPA/US@EPA  
cc: "Spaulding, Steve" <Steve.Spaulding@wellmarkint.com>  
bcc:  
Subject: RE: Zoecon RF 330 Altosid Pellets (272-448)

Mari, thanks for getting back to me. I'm sending you copies of paperwork (all in one PDF file) supporting our Aug 03 label amendment submission. There is a PDF of the original submission letter and 8570 form, and a copy of a Feb 04 email from Steve Spaulding to Linda Hollis documenting the discussions of Steve/BPPD's February 4 meeting. I have cut and pasted the email sections only relevant to the label amendment for the pellets (2724-448). Additionally, there's a copy of a BPPD Label Review Team Comment Sheet that was given to Steve at the meeting. I've also included a Word document (hilited) to show the areas of change based on the Comment Sheet from 2/4. There is also a PDF clean copy of the hilited version for stamping. If you have any questions, feel free to give me a call at 847-330-5376. Hopefully, we can finalize this action. Thanks for your help.

Nancy Huebl  
Wellmark International  
847-330-5376

-----Original Message-----

From: Duggard.Mari@epamail.epa.gov [mailto:Duggard.Mari@epamail.epa.gov]

Sent: Friday, November 12, 2004 8:29 AM  
To: Huebl, Nancy  
Cc: Spaulding, Steve  
Subject: RE: Zoecon RF 292 Briquet (272-421)

Hi Nancy,

Per our discussion a few moments ago, please electronically send me a copy of the amendment request to revise the First Aid statements for 2724-448. Also, please accept my apologies on behalf of the Agency and the Fast Track Team in BPPD that this submission has taken so long to process. I'll do my best to expedite upon receipt.

Regards,  
Mari Duggard  
Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division 7511C  
703-308-0028

"Huebl, Nancy"  
<Nancy.Huebl@wellmarkint.com>

11/08/04 03:11 PM

To  
Mari Duggard/DC/USEPA/US@EPA  
cc  
"Spaulding, Steve"  
<Steve.Spaulding@wellmarkint.com>  
Subject  
RE: Zoecon RF 292 Briquet  
(272-421)



Hi Mari, now that Chris Pfeifer that called to let me know that 2724-375 amendment has been finalized, was just checking on the amendment (First Aid, etc.) mentioned in your email below. Additionally, there is another First Aid amendment pending on 2724-448. All of these 3 amendments were submitted at the same time to EPA on 8/15/03. Could you give me an idea of the review status on the 421 and 448? Thanks for your help.

Nancy Huebl  
Wellmark International  
847 330 5376

Original Message

From: Duggard.Mari@epamail.epa.gov [mailto:Duggard.Mari@epamail.epa.gov]

Sent: Wednesday, September 22, 2004 8:41 AM  
To: Huebl, Nancy  
Subject: RE: Zoecon RF 292 Briquet (272 421)

Hi Nancy,

I'm reviewing the request to update First Aid and precautionary statements per PRN 2001 1 and the modify Directions for use. I am writing to request that you send me a clean copy of the draft label via electronic PDF attachment.  
(Same msg. per voicemail msg. of 22 Sep 04.)

Thanks,  
Mari Duggard  
Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511C)  
703 308-0028

NOTE: Beginning November 1, 2004 Wellmark International's new address for our corporate headquarters will be:

Wellmark International  
1501 E. Woodfield Rd.  
Suite 200W  
Schaumburg, IL 60173

Our phone numbers and Toll Free numbers will remain the same. Please contact the sender if you have any questions.

\*\*\*\*\*

This communication (including attachments) contains private, confidential, privileged and/or proprietary information intended solely for the Recipient (s) named above. If you are not the intended Recipient, any use, dissemination, distribution or copying of the communication is strictly prohibited. If received in error, we apologize

and ask that you please notify the Sender by calling 847/330-5300 or via return e-mail, permanently delete this communication from your computer and destroy any printed copies. Thank you in advance for your cooperation.

\*\*\*\*\*

Any views expressed herein are not necessarily those of Wellmark International. No contracts, agreements or legally binding understandings may be entered into solely by an e-mail communication.



2724-448 for EPA.pdf amend precautionary la eh with epa comments 204.doc amend precautionary fa eh with epa comments 204.pdf



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

I, Sheryl K. Reilly, Chief, Biochemical Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency (EPA), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product. Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration and/or the product label for the product listed below. EPA has issued a registration number for the product listed below to:

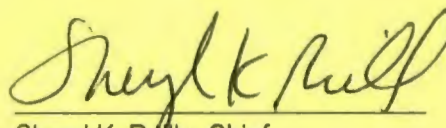
Wellmark International  
1100 East Woodfield Road, Suite 500  
Schaumburg IL 60173

EPA REGISTRATION NUMBER

2724-448

NAME OF PRODUCT

Zoecon RF0-330 Altosid Pellets



Sheryl K. Reilly, Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division

OCT 4 2004  
[Date]

CONCURRENCES							
SYMBOL	7511C	7511C					
SURNAME	Pollard	Reilly					
DATE	9/28/04	10/01/04					

# Wellmark

May 14, 2004

Ms. Sheryl Reilly  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Mall 2  
1921 Jefferson Davis Highway Room 266A  
Arlington VA 22202

**Subject: EPA Gold Seal Request**

Dear Ms. Reilly:

Our overseas affiliates are requesting verification of U.S. registration for four different Wellmark International products. At this time, Wellmark International respectfully requests a proof of registration letter bearing the EPA Gold Seal for the products listed below:

<u>Product</u>	<u>EPA Reg. No.</u>
Zoecon RF-292 Briquet	2724-421 ✓
S-Methoprene Technical	2724-442 ✓
Zoecon RFU-330 Altosid Pellets	2724-448 ✓
RF-9605 S-Methoprene Bait	2724-475

Because of duplicate requests for these products, please provide us with two (2) copies of each certificate. Please return the documents in the enclosed self-addressed stamped envelope.

Should you have any questions, please feel free to contact me directly at 847.330.5378 or jackie.richardson@wellmarkint.com.

Thank you,



Jackie Richardson  
Registration Specialist  
Wellmark International

enclosure



Complies With EPA  
Accepted Labeling Dated 7/29/97  
Reviewed By Opallard

FOR USE ONLY IN THE  
STATE OF NEW YORK



# Altosid<sup>®</sup> PELLETS

## MOSQUITO GROWTH REGULATOR

### A GRANULAR PRODUCT TO PREVENT ADULT MOSQUITO EMERGENCE

ACTIVE INGREDIENT: (S) - Methoprene [isopropyl (2E, 4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]: . . . 4.25%  
OTHER INGREDIENTS: . . . 95.75%  
TOTAL: . . . 100.00%

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**  
NET WT 22 LBS (10 kg)

#### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

##### CAUTION

##### ENVIRONMENTAL HAZARDS

Do not apply to known fish habitats. This product is toxic to aquatic dipteran. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of residue or equipment washwaters.

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID<sup>®</sup> PELLETS release ALTOSID<sup>®</sup> Insect Growth Regulator as they erode. The pellets prevent the emergence of adult standing water mosquitoes, including *Culex* and *Culiseta* spp., as well as adults of the floodwater mosquitoes (*Aedes*, *Anopheles* and *Psorophora* spp.) from treated sites.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die. NOTE: This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

##### APPLICATION SITES AND RATES:

HABITAT	RATES (Lb/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5.0
Dredging spoil sites, waste treatment and settling ponds, ditches and other manmade depressions	5.0 - 10.0
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5.0
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste	5.0 - 10.0

##### treatment settling ponds

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**Application Methods:** Apply ALTOSID PELLETS up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID PELLETS. The pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID PELLETS may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. **Storage:** Store closed containers of ALTOSID PELLETS in a cool, dry place. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information, call: 1-800-248-7763.

**Wellmark**

Bensenville, Illinois 60106

ALTOSID<sup>®</sup> Pellets, ALTOSID<sup>®</sup> Insect Growth Regulator and ZOECON<sup>®</sup> are registered trademarks of Wellmark International

Best if used by:

Lot No.

37775A

EPA Reg. No. 2724-448  
EPA Est. No. 2724-TX-1  
©2000 Wellmark International  
Made in USA

Complies With EPA  
Accepted Labeling Dated 7/29/97  
Reviewed By cpellard



# Altosid<sup>®</sup> PELLETS

## MOSQUITO GROWTH REGULATOR

### A GRANULAR PRODUCT TO PREVENT ADULT MOSQUITO EMERGENCE

ACTIVE INGREDIENT: (S) - Methoprene (CAS #65733-16-6) ..... 4.25%  
OTHER INGREDIENTS: ..... 95.75%  
TOTAL: ..... 100.00%

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**  
NET WT 22 LBS (10 kg)

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID<sup>®</sup> Pellets release ALTOSID<sup>®</sup> Insect Growth Regulator as they erode. The pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquilleidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes, such as *Aedes* and *Psorophora* spp. from treated sites.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die. **NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

**APPLICATION SITES AND RATES:** Use lower rates when water is shallow, vegetation and/or pollution are minimal, and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high, and mosquito populations are high.

MOSQUITO HABITAT	RATES (Lb/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, cattail marshes, woodland pools, floodplains, tires, other artificial water-holding containers	2.5 - 5.0
Dredging spoil sites, waste treatment and settling ponds, ditches and other manmade depressions	5.0 - 10.0
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, fish ponds, cattail marshes, water hyacinth beds, flooded crypts, transformer vaults, abandoned swimming pools, construction and other manmade depressions, treeholes, other artificial water-holding containers	2.5 - 5.0
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds, vegetation-choked phosphate pits	5.0 - 10.0

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding, or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10.0 lb/acre may be used to apply ALTOSID Pellets. The pellets

may also be applied using ground equipment which will achieve good even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers, such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. **Storage:** Store closed containers of ALTOSID Pellets in a cool dry place. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

#### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rinsate or equipment washwaters.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information, call: 1-800-248-7763.

Visit our Web site: [www.altosid.com](http://www.altosid.com)

**Wellmark**

Bensenville, Illinois 60106

EPA Reg. No. 7724-448  
EPA Est. No. 7724-TX-1  
©2000 Wellmark International  
Made in USA

ALTOSID<sup>®</sup> Pellets, ALTOSID<sup>®</sup> Insect Growth Regulator, and ZOECON<sup>®</sup> are registered trademarks of Wellmark International.

Best if used by:

Lot No.

03325G



Complies With EPA  
Accepted Labeling Dated 7/29/97  
Reviewed By cpelland

**STRIKE**  
**Pellets**  
**Prevents Nuisance Midge and Filter Fly Emergence**  
**Controls Waste Water Nuisance Pests**

**ACTIVE INGREDIENT:**  
(S)-Methoprene CAS# 65733-16-6 4.25%  
**OTHER INGREDIENTS:** 95.75%  
**TOTAL:** 100.00%

**NET CONTENTS:**  
22 LBS (10 kg)

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**  
See Additional Precautionary Statements

**ZOECON**

**INTRODUCTION:** STRIKE® Pellets are a unique product that controls filter flies (*Psychoda* spp.), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water facilities. STRIKE Pellets contain an Insect Growth Regulator (IGR) that is effective on the developing stages of insect pests. STRIKE Pellets do not kill adults but affects the larval stages as they grow and develop. STRIKE Pellets stop the formation of pupae of insect pests, thereby eliminating adult populations. STRIKE Pellets stop the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS:** STRIKE Pellets release effective levels of an Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on midges or filter flies which have reached the pupal or adult stage prior to treatment.

**APPLICATION SITES AND RATES:**

Use lower application rates when water is shallow, vegetation and/or pollution are minimal, and insect populations are low. Use higher rates when water is deep (>2 ft), vegetation, pollution, and/or organic debris or water flow are high, and insect populations are high. In instances of high organic debris and water flow, residual activity may be diminished.

<b>FILTER FLY / MIDGE HABITAT</b>	<b>RATES (lb/acre)</b>
Filter flies and midges are waste water treatment pests inhabiting sludge drying beds, clarifiers, holding tanks or ponds, sewage lagoons, evisceration ponds, paper or food waste ponds, stagnant or standing water, or other areas of waste water treatment facilities where midges, filter flies, and other nuisance aquatic insect pests are a problem.	5-10

**APPLICATION METHODS**

**Midges:** Apply STRIKE Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 5 to 10 lb/acre may be used to apply STRIKE Pellets. The pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates.

**Waste Water Nuisance Pests:** For applications to solid waste, including sludge and retention ponds, the initial high rate of 10 lb/acre is recommended. Immediately following filling of the drying beds, application of the product should be made uniformly to the surface of the bed. Application of STRIKE Pellets to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

For applications in aquatic habitats, including waste water treatment facilities, evisceration ponds, sewage lagoons, manure runoff areas, retention ponds, and holding tanks, apply STRIKE Pellets as uniformly as possible over the entire surface. In situations where the

ponds are large, applications made around the perimeter of the ponds can be helpful in reducing pests. In these situations, make applications up to a 20 foot band out from the bank around the pond perimeter.

STRIKE Pellets may be applied by using suitable application equipment, such as, hand or motorized spreaders, backpack blowers, or aircraft (rotary or fixed wing). Even coverage over the surface of the area to be treated is critical for optimum performance.

**What to Expect in Waste Water Facilities:** Following initial applications of STRIKE Pellets, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be noticeable within a 2 week period following the application. Due to varying conditions or heavy infestations, the period to expect control may be longer. Since the mode of action of STRIKE Pellets is to prevent adult emergence, existing adults and pupae present at the time of initial application will complete their life cycle.

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. Store closed containers of STRIKE Pellets in a cool dry place. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**CAUTION**

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rinsate or equipment washwaters.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information or in case of an emergency, call 1-800-877-6374.

Visit our website at [www.strike-zoecon.com](http://www.strike-zoecon.com)

**Wellmark**

Schaumburg, Illinois 60173

STRIKE® Pellets and ZOECON® are registered trademarks of Wellmark International

Best if used by:

Lot No.

37725A

EPA Reg. No. 2724-448  
EPA Est. No. 2724-TX-1  
©2001 Wellmark International  
Made in USA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 30 2004

Mr. Steve Spaulding  
Wellmark International  
100 East Woodfield Road, Suite 500  
Schaumburg, Illinois 60173

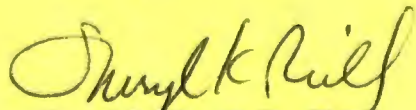
Subject: Application to Amend Confidential Statement of Formula Certified Limits  
Zoecon RF-330 Altosid Pellets  
EPA Reg. No. 2724-448  
Your submission of June 30, 2004 and resubmission August 24, 2004.

Dear Mr Spaulding.

The Confidential Statement of Formula referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is **acceptable**. The revised Confidential Statement of Formula (CSF) has been added to your file as current and updated.

Should you have questions concerning this action, please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product at (703) 308-1259.

Sincerely,



Sheryl Reilly, Ph.D., Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511C)

CONCURRENCES

SYMBOL	7511C	7511C					
SURNAME	LM	Reilly					
DATE	8/26/04	8/30/04					



Wellmark International  
1100 East Woodfield Road, Suite 300  
Schaumburg, Illinois 60193  
847 330 5300  
www.wellmarkint.com

Wellmark

August 24, 2004

Mr. Raderrio Wilkins (BY FAX @ 703-308-7026)  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (H7504C)  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

**SUBJECT: Zoecon RF-330 Altosid Pellets (EPA Reg. No. 2724-448)  
Formulation Amendment – Extension of Certified Limits  
Revised Confidential Statement of Formula (CSF)**

Dear Mr. Wilkins:

As a followup to our telephone conversation today, please find a revised CSF for Zoecon RF330-Altosid Pellets including the CAS # for [REDACTED] which was inadvertently omitted from the original CSF and a correction in the purpose in the formulation for [REDACTED] from antioxidant to preservative designated in Column 15 on the CSF.

The revised CSF dated August 24, 2004 included with this correspondence supercedes the CSF dated June 30, 2004 which was included in the original submission.

Please contact me by telephone at (847) 330-5380, by fax at (847) 330-5315 or by e-mail at [steve.spaulding@wellmarkint.com](mailto:steve.spaulding@wellmarkint.com) if you have any questions.

Sincerely yours,

Steven R. Spaulding  
Director, Regulatory Affairs

99

\*Inert ingredient information may be entitled to confidential treatment\*

**Confidential Business Information**

**Memorandum**

**Subject:** Application for extension of the certified limits for Zoecon RF-330 Altosid Pellets, EPA Reg. No. 2724-448. Active Ingredient: (s)-Methoprene, Chemical Code 105402, CASRN 65733-16-6. Submission # 763148. MRID 463213-01. CSF dated 06/03/2004.

**From:** Nina Simeonova, Chemist *N. Simeonova 08/02/2007*  
Biopesticides and Pollution Prevention Division  
Biochemical Pesticides

**To:** Raderrio Wilkins, RAL  
Biopesticides and Pollution Prevention Division  
Biochemical Pesticides

**Action Requested**

Wellmark International requests broader than the standard certified limits ( $\pm 10\%$  instead of  $\pm 5\%$ ) for the active ingredient and addition of an alternative manufacturing site for the product Zoecon RF-330 Altosid Pellets, EPA Reg. No. 2724-448. The active ingredient is (s)-Methoprene in nominal concentration 4.25 % in the form of pellets. It is marketed as larvicide against mosquitos and midges and has food/feed and non-food uses. To support the request the registrant submitted the study "Zoecon RF-330 Altosid Pellets Certified Limits" MRID 463213-01 and a CSF, containing the requested changes.

**Studies Summary**

Statistical analysis of the variations of the nominal concentration of (s)-Methoprene in the pellets from 78 industrial scale pelletizations shows that due to some intrinsic refractory properties of the mixture of (s)-Methoprene, [REDACTED] the enforceable certified limits for the active ingredient must be  $\pm 10\%$  in order to achieve a level of process capability 1.0 or greater. The statistical analysis is based on a large number of data and is reliable. There is enough evidence that due to manufacturing difficulties, specific for this formulation the enforceable certified limits must be set at  $\pm 10\%$  to achieve process capability of 1.01.

There are no mistakes or deficiencies in the proposed CSF, except that [REDACTED]



■ is a preservative, not an antioxidant in the formulation.

### **Recommendations and conclusions**

The request is acceptable, because it is well motivated with the results from the appropriate statistical treatment of 78 results about the concentration of (s)-Methoprene, obtained from the manufacturing practice. It meets all the requirements of 40CFR§158.175 (c), "Applicant proposed limits". The addition of alternative production site is also acceptable. It is desirable to correct the data about ■ in Column 15 from 'antioxidant' to 'preservative' and to provide the CASRN for the ingredient ■

cc: Nina Simeonova to Raderrio Wilkins  
Nina Simeonova, CM2 , (703) 308-0291; 08/02/2004.

## MEMORANDUM

DATE: 7 / 19 / 04

TO: BPPD, Regulatory Manager

FROM: Information Services Branch, IRSD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately two weeks from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Maureen Sherrill (305-5361) or Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission



# Fee for Service

This package includes the following

for Division

☒ New FFS Action

☒ Amendment

☐ Waiver Request

☒ Voluntary Payment Request

☐ RD

☐ AD

☒ BPPD

Receipt Nos. S- 763148

Product/Risk Manager: 91

EPA File Symbol/Reg. No. 2724-448

Pin-Punch Date: 7-1-04

☐ This item is NOT subject to FFS action.

Action Code: B68

Amount Due: \$ 4,000

Voluntary Payment Reduction Amount:

☐ 0%

☐ 40%

☐ 80%

☐ 10%

☐ 50%

☐ 90%

☐ 20%

☐ 60%

☐ 100%

☐ 25%

☐ 70%

☐ Other

☐ 30%

☐ 75%

\_\_\_\_ %

Original Decision #:

D- \_\_\_\_\_

Reviewer: S. Reilly

Date: 7/16/04

Remarks:

*Jdm note*  
This is not a vol pay-

This is a new, non-FT amendment  
(with data) - S. Reilly



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-448	2. EPA Product Manager S. Reilly	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Zoecon RF-330 Altosid Pellets	PM # Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1100 East Woodfield Road, Suite 500 Schaumburg, Illinois 60173  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and section II.)

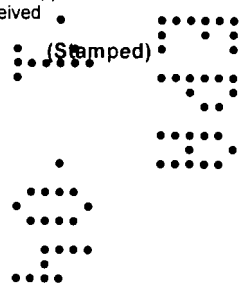
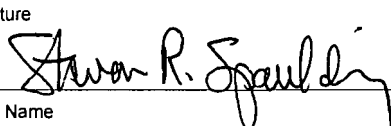
Non-Fast Track, Formulation Amendment to Extend the Certified Limits  
Category B68  
Fee \$4,000

Contact Name: Steve Spaulding  
Contact Email: steve.spaulding@wellmarkint.com  
Contact Phone: 847.330.5380  
Contact Fax: 847.330.5315

## Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted					
3. Location of Net Contents Information  <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 to 100 lbs.		5. Location of Label Directions  <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Steven R. Spaulding	Title Director, Regulatory Affairs	Telephone No. (Include Area Code) 847.330.5380
<b>Certification</b>  I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received 
2. Signature 	3. Title Director, Regulatory Affairs	
4. Typed Name Steven R. Spaulding	5. Date 30-Jun-04	



# FEE FOR SERVICE

B68

Now: FAST/PRIA

Andy

PRIA  
Action code

(Andy - check w/ Carole Pollard who has been handling previous related submission - Nina should review this.)



June 30, 2004

Document Processing Desk (REGFEE)  
Office of Pesticide Programs (H7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

ATTN: Dr. Sheryl Reilly, Branch Chief Biochemicals  
Biopesticides and Pollution Prevention Division

SUBJECT: Zoecon RF-330 Altosid Pellets (EPA Reg. No. 2724-448)  
Formulation Amendment – Extension of Certified Limits

Dear Dr. Reilly:

This application for a Non-Fast Track Amendment for Zoecon RF-330 Altosid Pellets (EPA Reg. No. 2724-448) is being submitted under PRIA Category B68 (\$4000 / 6 mo. review). The purpose of this amendment is to extend the certified limits for the active ingredient (S)-Methoprene from +/- 5% as outlined in 40CFR 158.175 to +/- 10%. The wider than standard limits are necessary due to variability during the manufacturing process and batch data to support the extended limits are included in Study 2960 which is submitted with this application. An overview of the current and proposed limits is as follows:

CSF Version	Nominal	Upper Certified Limit	Lower Certified Limit
Current – 6/23/04	4.25%	4.46%	4.04%
Proposed – 6/30/04	4.25%	4.68%	3.82%

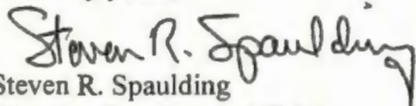
We have also added the Wellmark manufacturing facility in Dallas, Texas to the CSF as an alternate production site.

The following documentation is included with this application:

1. Application for Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (2 copies)
3. Transmittal Document and 1 Supportive Study (3 copies)

Please contact me by telephone at (847) 330-5380, by fax at (847) 330-5315 or by e-mail at [steve.spaulding@wellmarkint.com](mailto:steve.spaulding@wellmarkint.com) if you have any questions.

Sincerely yours,

  
Steven R. Spaulding  
Director, Regulatory Affairs



**TRANSMITTAL DOCUMENT**

**SUBMITTED BY**

Wellmark International  
1100 East Woodfield Road  
Schaumburg, Illinois 60173

**REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS  
SUBMITTED**

Non-Fast Track Amendment to Extend the Certified Limits for Zoecon RF-330  
Altosid Pellets (EPA Reg. No. 2724-448)

**TRANSMITTAL DATE**

June 30, 2004

**LIST OF SUBMITTED STUDIES**

Volume 1 of 1. McDaniel, J. Zoecon RF-330 Altosid Pellets Certified Limits.  
OPPTS 830.1750. Wellmark Study No. 2960. June 2004.

46321301

**COMPANY OFFICIAL:**

Steven R. Spaulding  
Director, Regulatory Affairs

*Steven R. Spaulding*

**COMPANY NAME:**

Wellmark International

**COMPANY CONTACT:**

Steven R. Spaulding (847) 330-5380

Administrative

Materials





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

July 19, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-346377  
EPA File Symbol or Registration Number: 2724-448  
Product Name: ZOECON RF-330 ALTOSID PELLETS  
EPA Receipt Date: 01-Jul-2004  
EPA Company Number: 2724  
Company Name: WELLMARK INTERNATIONAL

STEVE SPAULDING  
WELLMARK INTERNATIONAL  
1100 EAST WOODFIELD ROAD, SUITE 500  
SCHAUMBURG, IL 60173

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B68

AMENDMENT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;

Please remit payment in the amount of: \$ 4,000 to:

By USPS:  
USEPA Washington Finance Center  
Pesticide Registration Service Fee  
PO Box 360277  
Pittsburgh, PA 15251

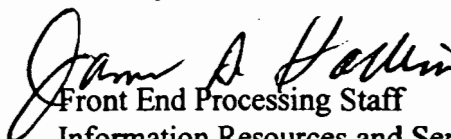
By Courier:  
U.S. EPA Washington Finance Center  
Pesticide Registration Service Fee  
C/O Mellon Client Service Center  
500 Ross Street, Room 670  
Box 360277  
Pittsburgh, PA 15251-6277  
Attn: EPA Module Supervisor  
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at [www.epa.gov/pesticides/fees](http://www.epa.gov/pesticides/fees).

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-8260.

Sincerely,



Front End Processing Staff  
Information Resources and Services Division

# Wellmark

June 30, 2004

Document Processing Desk (REGFEE)  
Office of Pesticide Programs (H7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

ATTN: Dr. Sheryl Reilly, Branch Chief Biochemicals  
Biopesticides and Pollution Prevention Division

SUBJECT: **Zoecon RF-330 Altosid Pellets (EPA Reg. No. 2724-448)**  
**Formulation Amendment – Extension of Certified Limits**

Dear Dr. Reilly:

This application for a Non-Fast Track Amendment for Zoecon RF-330 Altosid Pellets (EPA Reg. No. 2724-448) is being submitted under PRIA Category B68 (\$4000 / 6 mo. review). The purpose of this amendment is to extend the certified limits for the active ingredient (S)-Methoprene from +/- 5% as outlined in 40CFR 158.175 to +/- 10%. The wider than standard limits are necessary due to variability during the manufacturing process and batch data to support the extended limits are included in Study 2960 which is submitted with this application. An overview of the current and proposed limits is as follows:

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Proposed – 6/30/04	4.25%	4.68%	3.82%

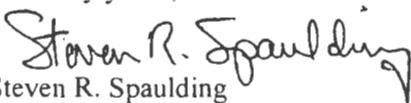
We have also added the Wellmark manufacturing facility in Dallas, Texas to the CSF as an alternate production site.

The following documentation is included with this application:

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2. Confidential Statement of Formula (2 copies)
3. Transmittal Document and 1 Supportive Study (3 copies)

Please contact me by telephone at (847) 330-5380, by fax at (847) 330-5315 or by e-mail at [steve.spaulding@wellmarkintl.com](mailto:steve.spaulding@wellmarkintl.com), if you have any questions.

Sincerely yours,

  
Steven R. Spaulding  
Director, Regulatory Affairs



**TRANSMITTAL DOCUMENT**

**SUBMITTED BY**

Wellmark International  
1100 East Woodfield Road  
Schaumburg, Illinois 60173

**REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS  
SUBMITTED**

Non-Fast Track Amendment to Extend the Certified Limits for Zoecon RF-330  
Altosid Pellets (EPA Reg. No. 2724-448)

**TRANSMITTAL DATE**

June 30, 2004

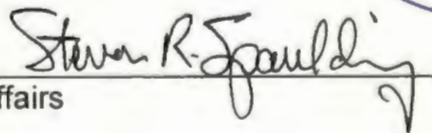
**LIST OF SUBMITTED STUDIES**

Volume 1 of 1. McDaniel, J. Zoecon RF-330 Altosid Pellets Certified Limits.  
OPPTS 830.1750. Wellmark Study No. 2960. June 2004.

46321301

**COMPANY OFFICIAL:**

Steven R. Spaulding  
Director, Regulatory Affairs



**COMPANY NAME:**

Wellmark International

**COMPANY CONTACT:**

Steven R. Spaulding (847) 330-5380

5762853



June 24, 2004

Sent via FedEx

Ms. Carole Pollard (7511C)  
U.S. EPA, OPP, DPD  
1921 Jefferson Davis Highway  
Crystal Mall 2, Room 266A  
Arlington VA 22202-4501

*Notification*

**Subject: Zoecon RF-330 Altosid Pellets – EPA Reg. No. 2724-448  
Formulation Amendment – Updated and Revised Basic CSF  
Submission of CAS# Correction**

Ms. Pollard:

Per your email discussions with Steve Spaulding, please find enclosed two copies of the corrected CSF for the subject Wellmark registration. As agreed, the only correction made was to the CAS# for [REDACTED]. The CAS# now reflects [REDACTED].

We appreciate your assistance with this formulation amendment. Should you have any questions, or need additional information, please feel free to contact Steve directly at 847.330.5380 or [steve.spaulding@wellmarkint.com](mailto:steve.spaulding@wellmarkint.com).

Thank you,

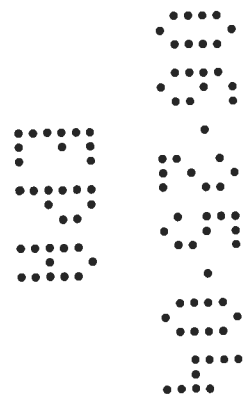
*Jackie Richardson*

Jackie Richardson  
Registration Specialist  
Wellmark International

*Pollard  
345*

enclosure

**NOTIFICATION**  
Date Reviewed: 7/29/04  
Reviewed By: CP



\*Inert ingredient information may be entitled to confidential treatment\*



**Carole Pollard**

06/23/2004 02:17 PM

To: steve.spaulding@wellmarkint.com  
cc: Linda Hollis  
Subject: Re: FW: EPA Registration No. 2724-448

Steve Spaulding -

Your justification is correct. All you need to do is to send me a new CSF with the correction mentioned under "A" in my email of February 11, 2004.

As stated before, in order to expedite the processing time, you can fax this information to me. As you know the CSF contains Confidential Business Information (CBI) and we do not typically suggest that information containing CBI be faxed because we cannot guarantee security of the information. We understand however that receiving this information expeditiously would greatly help in the timeliness of your resubmission.

If you wish to fax this information to the Agency, please send an email back to me stating that you will be faxing the information. Also please send a carbon copy to my team leader, Ms. Linda Hollis, hollis.linda@epa.gov. In your email be sure to state that you understand that the resubmission contains CBI, and the Agency cannot guarantee the security of the information. Also state that you waive (for this time only) any of the Agency's responsibility concerning the security of this application.

Furthermore, if you do not want to send a fax, due to CBI, then you may either: send the application and CSF by Federal Express to:  
Document Processing Desk, Office of Pesticide Programs, U.S.  
Environmental Protection Agency, Room 266A, 1921 Jefferson-Davis Highway, Crystal Mall 2,  
Arlington, VA 22202-4501, Attention: Carole Pollard (7511C); or if you want to use regular mail send the package to:  
Carole Pollard (7511C), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW,  
Washington, DC 20460.

Thank you.  
Carole Pollard  
703-308-0411

Linda Hollis

**Linda Hollis**

06/22/2004 02:43 PM

To: Carole Pollard/DC/USEPA/US@EPA  
cc:  
Subject: FW: EPA Registration No. 2724-448

have you wrapped this up?

----- Forwarded by Linda Hollis/DC/USEPA/US on 06/22/2004 02:45 PM -----



**"Spaulding, Steve"**  
<Steve.Spaulding@wellmarkint.com>

06/22/2004 02:20 PM

To: Linda Hollis/DC/USEPA/US@EPA  
cc:  
Subject: FW: EPA Registration No. 2724-448



Linda - here is my last response to Carol Pollard in February concerning the formulation amendment for 2724-448. Could you please check and see where this one is at.

Also received a fax with some comments on it for the amendment for 2724-352 that we discussed this morning. I will discuss it with our formulation chemist and get back to you soon.

Thanks, Steve

-----Original Message-----

From: Spaulding, Steve  
Sent: Friday, February 13, 2004 8:43 AM  
To: 'Pollard.Carole@epamail.epa.gov'  
Subject: RE: EPA Registration No. 2724-448

Dear Carole - thank you for the comments on the CSF for 2724-448.

I checked the CSF we submitted and confirm that the correct CAS# for the [REDACTED] should be [REDACTED] as mentioned under "A" in your e-mail. Thanks for pointing out this "typo".

We are confused by your comments under "B" and "C". I discussed this with our formulation chemist and he sent me the attached monograph from the Chemical Abstracts Registry where it identifies [REDACTED] as the CAS# for the [REDACTED]. Therefore, I do not see any need to correct anything on the CSF other than the "typo". Please let me know if you agree and then we can send you a corrected CSF.

Thanks for your help.  
Steve

\*\*\*\*\*  
Steven R. Spaulding  
Director, Regulatory Affairs  
Wellmark International  
847.330.5380 ph  
847.330.5315 fx  
\*\*\*\*\*

-----Original Message-----

From: Pollard.Carole@epamail.epa.gov  
[mailto:Pollard.Carole@epamail.epa.gov]  
Sent: Wednesday, February 11, 2004 9:27 AM  
To: Spaulding, Steve  
Subject: EPA Registration No. 2724-448

Mr. Spaulding

Subject: EPA Registration No. 2724-448  
Product Name: Zoecon RF-330 Altosid Pellets  
RE: Amendment - Updated and Revised Basic Confidential  
Statement of Formula Dated July 30, 2003

According to PRN 98-10, the changes you submitted to the CSF for this product can be accomplished through notification. However, these changes are

not acceptable under a notification for the reasons given below. Please make the changes requested to the CSF under column 10.

- A. Under (b) [REDACTED] the CAS# should be: [REDACTED]
- B. Delete (c) [REDACTED] because it is incorrect.
- C. Add (c) [REDACTED], CAS# [REDACTED]

In order to expedite the processing time, you can fax this information to me. As you know the CSF contains Confidential Business Information (CBI) and we do not typically suggest that information containing CBI be faxed because we cannot guarantee security of the information. We understand however that receiving this information expeditiously would greatly help in the timeliness of your resubmission.

If you wish to fax this information to the Agency, please send an email back to me stating that you will be faxing the information. Also please send a carbon copy to my team leader, Ms. Linda Hollis, hollis.linda@epa.gov). In your email be sure to state that you understand that the resubmission contains CBI, and the Agency cannot guarantee the security of the information. Also state that you waive (for this time only) any of the Agency's responsibility concerning the security of this application.

Furthermore, if you do not want to send a fax, due to CBI, then you may either: send the application and CSF by Federal Express to: Document Processing Desk, Office of Pesticide Programs, U.S. Environmental Protection Agency, Room 266A, 1921 Jefferson-Davis Highway, Crystal Mall 2, Arlington, VA 22202-4501, Attention: Carole Pollard (7511C); or if you want to use regular mail send the package to: Carole Pollard (7511C), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

Thank you.  
Carole Pollard  
703-308-0411

\*\*\*\*\*

This communication (including attachments) contains private, confidential, privileged and/or proprietary information intended solely for the Recipient (s) named above. If you are not the intended Recipient, any use, dissemination, distribution or copying of the communication is strictly prohibited. If received in error, we apologize and ask that you please notify the Sender by calling 847/330-5300 or via return e-mail, permanently delete this communication from your computer and destroy any printed copies. Thank you in advance for your cooperation.

\*\*\*\*\*

Any views expressed herein are not necessarily those of Wellmark International. No contracts, agreements or legally binding understandings may be entered into solely by an e-mail communication.



CAS Number for [REDACTED]







"Spaulding, Steve"  
<Steve.Spaulding@wellmarkint.com>

02/13/2004 09:43 AM

To: Carole Pollard/DC/USEPA/US@EPA  
CC:  
Subject: RE: EPA Registration No. 2724-448

Dear Carole - thank you for the comments on the CSF for 2724-448.

I checked the CSF we submitted and confirm that the correct CAS# for the [REDACTED] should be [REDACTED] as mentioned under "A" in your e-mail. Thanks for pointing out this "typo".

We are confused by your comments under "B" and "C". I discussed this with our formulation chemist and he sent me the attached monograph from the Chemical Abstracts Registry where it identifies [REDACTED] as the CAS# for the [REDACTED]. Therefore, I do not see any need to correct anything on the CSF other than the "typo". Please let me know if you agree and then we can send you a corrected CSF.

Thanks for your help.  
Steve

\*\*\*\*\*  
Steven R. Spaulding  
Director, Regulatory Affairs  
Wellmark International  
847.330.5380 ph  
847.330.5315 fx  
\*\*\*\*\*

-----Original Message-----

From: Pollard.Carole@epamail.epa.gov  
[mailto:Pollard.Carole@epamail.epa.gov]  
Sent: Wednesday, February 11, 2004 9:27 AM  
To: Spaulding, Steve  
Subject: EPA Registration No. 2724-448

Mr. Spaulding

Subject: EPA Registration No. 2724-448  
Product Name: Zoecon RF-330 Altosid Pellets  
RE: Amendment - Updated and Revised Basic Confidential  
Statement of Formula Dated July 30, 2003

According to PRN 98-10, the changes you submitted to the CSF for this product can be accomplished through notification. However, these changes are not acceptable under a notification for the reasons given below. Please make the changes requested to the CSF under column 10.

- A. Under (b) [REDACTED] the CAS# should be: [REDACTED] OK
- B. Delete (c) [REDACTED] because it is incorrect.
- C. Add (c) [REDACTED]

In order to expedite the processing time, you can fax this information to me. As you know the CSF contains Confidential Business

PE  
6/23/04

**\*Inert ingredient information may be entitled to confidential treatment\***

Information (CBI) and we do not typically suggest that information containing CBI be faxed because we cannot guarantee security of the information. We understand however that receiving this information expeditiously would greatly help in the timeliness of your resubmission.

If you wish to fax this information to the Agency, please send an email back to me stating that you will be faxing the information. Also please send a carbon copy to my team leader, Ms. Linda Hollis, hollis.linda@epa.gov). In your email be sure to state that you understand that the resubmission contains CBI, and the Agency cannot guarantee the security of the information. Also state that you waive (for this time only) any of the Agency's responsibility concerning the security of this application.

Furthermore, if you do not want to send a fax, due to CBI, then you may either: send the application and CSF by Federal Express to: Document Processing Desk, Office of Pesticide Programs, U.S. Environmental Protection Agency, Room 266A, 1921 Jefferson-Davis Highway, Crystal Mall 2, Arlington, VA 22202-4501, Attention: Carole Pollard (7511C); or if you want to use regular mail send the package to: Carole Pollard (7511C), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

Thank you.

Carole Pollard  
703-308-0411



CAS Number for [REDACTED]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 1, 2003

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

STEVE SPAULDING  
WELLMARK INTERNATIONAL  
1100 EAST WOODFIELD ROAD, SUITE 500  
SCHAUMBURG, IL 60173

PRODUCT NAME: ZOECON RF-330 ALTOSID PELLETS  
COMPANY NAME: WELLMARK INTERNATIONAL  
EPA FILE SYMBOL: 2724-448  
EPA RECEIPT DATE: 08/01/03

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-8269.

Sincerely,

A handwritten signature in blue ink, appearing to read "J. Alrice".

Front End Processing Staff  
Information Services Branch  
Information Resources and Services Division





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-448	2. EPA Product Manager S. Reilly	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Zoecon RF-330 Altosid Pellets	PM # Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1100 East Woodfield Road, Suite 500 Schaumburg, Illinois 60173  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and section II.)

Formulation Amendment - Updated and Revised Basic Confidential Statement of Formula

*This was treated as a notification.*

## Section - III

1. Material This Product Will be Packaged In:			2. Type of Container	
Child-Resistant Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted If "Yes" Unit No. per Packaging wgt. container				
3. Location of Net Contents Information  <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 to 100 lbs		5. Location of Label Directions  <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product
6. Manner in Which Label is Affixed to Product  <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Steven R. Spaulding	Title Director, Regulatory Affairs	Telephone No. (Include Area Code) 847.330.5380
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
2. Signature <i>Steven R. Spaulding</i>	3. Title Director, Regulatory Affairs	
4. Typed Name Steven R. Spaulding	5. Date 30-Jul-03	



\*Inert ingredient information may be entitled to confidential treatment\*

Wellmark

July 30, 2003

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

ATTN: Dr. Sheryl Reilly, Branch Chief Biochemicals  
Biopesticides and Pollution Prevention Division

SUBJECT: **Zoecon RF-330 Altosid Pellets (EPA Reg. No. 2724-448)**  
**Formulation Amendment – Updated and Revised Basic Confidential**  
**Statement of formula (CSF)**

Dear Dr. Reilly:

Please find enclosed an amendment to update and revise the Basic CSF for Zoecon RF-330 Altosid Pellets (EPA Reg. No. 2724-448). The following changes have been made to the CSF:

- ok 1. Update address for Wellmark International
- ok 2. Update name of Producer to Schirm, Inc. The address remains the same.
- ok 3. Update S-Methoprene supplier name and address to reflect Wellmark International.
- ok 4. Provide supplier names and addresses for all inert ingredients.
- 5. Addition of alternate forms of [REDACTED] in addition to [REDACTED]  
[REDACTED] which is included on the current CSF.

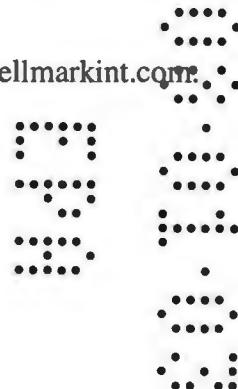
- [REDACTED]
- [REDACTED]

Two (2) copies of the revised Basic CSF are enclosed with this amendment as well as a copy of the Basic CSF currently on file with the Agency dated September 4, 1997 as a point of reference.

Please contact me at (847) 330-5380 or by e-mail at [steve.spaulding@wellmarkint.com](mailto:steve.spaulding@wellmarkint.com) if you have any questions.

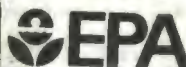
Sincerely yours,

*Steven R. Spaulding*  
Steven R. Spaulding  
Director, Regulatory Affairs









203585  
U.S. ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAMS (TS-767)  
WASHINGTON, DC 20460

# NOTICE OF SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR

(Please read instructions before completing)

## INSTRUCTIONS

After a registrant has obtained final registration for the basic product, the registrant may then supplementally register and distribute his/her product. One form must be submitted for each distributor brand and must be signed by the distributor involved. The form must state the basic registration number and the distributor company number.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting a Distributor Notification to the Agency.

Notification forms must be submitted by the basic registrant. They must have the concurrence and signature of both the registrant and the distributor.

When submitting several forms for the same basic product, submitting them together will facilitate processing.

**NOTE: DO NOT** submit distributor product labels.

## CONDITIONS

1. The distributor product must have the same composition as the basic registered product.
2. The distributor brand product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so no other changes are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic registered product, followed by a hyphen and the distributor's company number.
6. Distributor products must bear the name and address of the distributor qualified by such terms as "packed for . . .," "distributed by . . ."; or "sold by . . ." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor brand products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

EPA REGISTRATION NO. OF PRODUCT	DISTRIBUTOR COMPANY NUMBER
3 2724-448	64833 7

NAME AND ADDRESS OF BASIC REGISTRANT (print or type; include ZIP code)

Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive  
Dallas, Texas 75234

NAME OF REGISTERED PRODUCT (basic product name accepted by EPA)

Zoecon RF-330 Altosid Pellets

DISTRIBUTOR PRODUCT NAME

Zoecon Altosid Pellets

NAME AND ADDRESS OF DISTRIBUTOR (print or type; include ZIP code)

Vector Management Division  
A Division of Zoecon Corporation  
12200 Denton Drive  
Dallas, Texas 75234

## DISTRIBUTOR

We intend to market under the Distributor Product Name and Number specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF DISTRIBUTOR	DATE
Patricia A. Howell, Regulatory Analyst	9/17/91

## REGISTRANT

It is requested that the Registration Record of this jacket include the Distributor Product specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF REGISTRANT	DATE
Patricia A. Howell, Regulatory Analyst	9/17/91

RECEIVED BY EPA REGISTRATION DIVISION ON THE DATE STAMPED BELOW

9-24-91



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 16 1999

Ms. Cathy Elmi  
Wellmark International  
Regulatory Affairs  
1000 Tower Lane  
Suite 245  
Bensenville, IL 60106

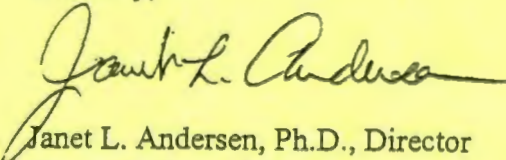
Dear Ms. Elmi:

Subject: Modification of Wellmark International's Altosid Solid Formulations (2724-448, 2724-375 and 2724-421) Fish Habitat Labeling Restriction Reinstatement

Thank you for your fax to Mr. Willie H. Nelson dated March 24, 1999, requesting a specific restriction for labeling to be used in New York to read, in the upper left hand corner of the front panel of your Altosid products labeling to state **"FOR USE ONLY IN THE STATE OF NEW YORK"** and to allow for the reinstatement, under the Environmental hazards Statement, **"Do not apply to known fish habitats"** to be added back onto the label. The request IS HEREBY GRANTED for one year from the stamped date of this letter.

Should you have any questions concerning this letter, please feel free to contact Mr. Willie H. Nelson at (703) 308-8682.

Sincerely,

  
Janet L. Andersen, Ph.D., Director  
Biopesticides and Pollution Prevention  
Division(7511C)

CONCURRENCES							
SYMBOL	W Nelson:308-8682:2724-448,375 and 421: methoprene:04/14/99						
SURNAME	Nelson						
DATE	04/16/99						





April 7, 1999

Document Processing Desk (NOTIF)  
Office of Pesticide Programs H7504C  
U.S. Environmental Protection Agency  
Room 266A Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202

ATTENTION: W. Nelson

SUBJECT: NOTIFICATION OF NEW YORK ONLY LABELS (FISH HABITAT RESTRICTION)  
FOR ZOECON ALTOSID® BRIQUET/EPA REG. NO. 2724-375  
FOR ZOECON RF-292 BRIQUET/EPA REG. NO. 2724-421  
FOR ZOECON RF-330 ALTOSID® PELLETS/EPA REG. NO. 2724-448

Dear Mr. Nelson:

Enclosed are completed EPA Forms 8570-1 and a copy of each of the above New York only labels to serve as notification (per your phone conversation of 4/7/99 with Cathy Elmi) that these labels (do not match current EPA stamped approved-Environmental Hazards) will be approved by the State of New York until they have reviewed/approved the data package submitted to New York to remove the fish habitat restriction.

If you have any questions please, call me (630/227-6017) or Cathy Elmi (630/227-6016). Thank you for your assistance in this matter.

Yours sincerely,  
WELLMARK INTERNATIONAL

A handwritten signature in cursive script that reads "Nancy Huebl".

Nancy Huebl  
Regulatory Label Specialist

enclosure

cc F. Hegener, State of New York  
C. Elmi



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-375	2. EPA Product Manager R. Sjoblad	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Zoecon Altosid Briquets	PM # Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1000 Tower Lane Bensenville, Illinois 60106  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Notification of use of New York only label (containing fish habitat restriction in Environmental Hazards-not matching current EPA approved label) until such time as NY reviews/approves data package to remove the fish habitat restriction.

## Section - III

1. Material This Product Will be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>berg cloth onion bag</u>		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Unit Packaging wgt.	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 lb to 100 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____					

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Nancy Huebl		Title Regulatory Label Specialist	
		Telephone No. (Include Area Code) (630) 227-6017	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped)
2. Signature <i>Nancy Huebl</i>		3. Title Regulatory Label Specialist	
4. Typed Name Nancy Huebl		5. Date 07-Apr-99	



FOR USE ONLY IN THE  
STATE OF NEW YORK



# Altosid®

## BRIQUETS

### A SUSTAINED RELEASE MOSQUITO GROWTH REGULATOR TO PREVENT ADULT MOSQUITO EMERGENCE

**ACTIVE INGREDIENT:** Methoprene [Isopropyl (E, E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate] (Dry Weight Basis) ..... 8.62%  
**OTHER INGREDIENTS:** ..... 91.38%  
**TOTAL:** ..... 100.00%  
 This product contains water, therefore the weight of the briquet and percent by weight of active ingredient will vary with hydration.  
 The Ingredient Statement is expressed on a dry weight basis.

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**PRECAUTIONS:** Do not apply to known fish habitats.  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**CAUTION**

**DIRECTIONS FOR USE:**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**STORAGE & DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. Storage: Store in cool, dry place. Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal: Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Note to User:** Do not remove ALTOSID Briquets from container except for immediate use.

Because of the unique mode of action of ALTOSID Briquets, users must be familiar with special techniques for accurate evaluation of treatments. See Application Rates and Intervals section of this label or consult local Mosquito Abatement Agency. Effective use of ALTOSID Briquets in sites subjected to periodic heavy flow of water requires careful attention to briquet placement and to the possible need for retreatment. Use of the product in storm drains, waste treatment and settling ponds, and similar systems should therefore be limited to experienced pesticide applicators such as personnel of Mosquito Abatement Districts and Public Health Agencies.

**Introduction:** The ALTOSID Briquet is a formulation designed to release effective levels of ALTOSID Insect Growth Regulator over a 30 day period under typical environmental conditions. Release of ALTOSID Insect Growth Regulator is effected by dissolution of the ALTOSID Briquet. Obstructions, such as debris, vegetation, and loose sediment can cover the briquets and inhibit normal dispersion of the active ingredient. Such obstructions may occur after high rainfall or flow. The product may not be effective in those situations where the briquet can be removed from the site by flushing action. ALTOSID Briquets prevent the emergence of adult mosquitoes including *Culex* and *Culiseta* spp., as well as those of the floodwater mosquito complex (*Aedes*, *Anopheles* and *Psorophora* spp.), from treated water. Treated larvae continue to develop normally to the pupal stage where they die.

**Application Time:** Placement of ALTOSID Briquets should be made at the beginning of the mosquito season. Under normal conditions repeat treatment every 30 days. Renew at the recommended interval and rate (see table). Continue treatment through the last brood of the season. Placement may be made at any stage of larval development. **NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

**Application Sites:** ALTOSID Briquets are designed to control mosquitoes in small bodies of water which are not known fish habitats. Examples of application sites are: storm drains, catch basins, roadside ditches, ornamental ponds and fountains, cesspools and septic tanks, waste treatment and settling ponds, flooded crypts, transformer vaults, abandoned swimming pools, construction and other manmade depressions, cattle marshes, water-hyacinth beds, pastures, meadows, rice fields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, flood plains and dredging spoil sites. For application sites connected by a water system, i.e., storm drains or catch basins, all of the water holding sites in the system should be treated to maximize the efficiency of the treatment program.

**Application rates and Intervals:** For mosquito control in non-(or low-) flow, shallow depressions (up to 2 ft. in depth), treat on the basis of surface area placing 1 ALTOSID Briquet per 100 sq. ft. For mosquito control in water subject to flow or deeper than 2 ft., treat on the basis of volume. Apply at the rate of 1 ALTOSID Briquet per 10 cu. ft. (75 gal. of water). ALTOSID Briquets will maintain an effective concentration throughout four complete volume changes per 30 day treatment interval according to the following table.

ALTOSID BRIQUETS FOR FLOWING WATER  
Volume/Treatment Rate/Flow

Maximum Water Volume in Application Site	Basic Application Rate (ALTOSID BRIQUETS)	Allowable FLOW for 30 day Mosquito Control
0-10 cu.ft. (75 gal.)	1	up to 300 gal.
10-20 cu.ft.	2	up to 600 gal.
20-30 cu.ft.	3	up to 900 gal.
30-40 cu.ft.	4	up to 1200 gal.

In the event of higher flow, reduce the treatment interval proportionately using the following flow formula. Do not increase the application rate.

**Flow Adjustment Formula**

$$\frac{\text{Allowable Flow}^*}{\text{Actual Flow}} \times 30 = \text{Adjusted Treatment Interval (days)}$$

\*4 volume changes or see table

Example: For a 36 cu. ft. catch basin of low flow (up to 1200 gal. per 30 days), treat with four ALTOSID Briquets. For higher flow, such as 2400 gal. per 30 days, the treatment interval should be reduced to 15 days (1200/2400 x 30 = 15).

Seller makes no warranty, express or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

**Wellmark**

Bensenville, Illinois 60106

EPA Reg. No. 2724-375  
 EPA Est. No. 38578-TX-1

©1999 Wellmark International

ALTOSID® Briquets, ALTOSID® Insect Growth Regulator and ZOECON®, are registered trademarks of Wellmark International.

For information, call 1-800-248-7783

37073

MINIMUM NET CONTENTS: 1.19 LBS. (540g) CONTAINS 100 BRIQUETS

BEST IF USED BY: \_\_\_\_\_





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-421	2. EPA Product Manager R. Sjoblad	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Zoecon RF-292 Briquet	PM # Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1000 Tower Lane Bensenville, Illinois 60106  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and section II.)

Notification of use of New York only label (containing fish habitat restriction in Environmental Hazards-not matching current EPA approved label) until such time as NY reviews/approves data package to remove the fish habitat restriction.

## Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>berg cloth onion bag</u>		
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 10 lbs - 100 lbs	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product		
6. Manner in Which Label is Affixed to Product  <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other <u>sewn to bag</u>			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Nancy Huebl	Title Regulatory Label Specialist	Telephone No. (Include Area Code) (630) 227-6017	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  <div style="text-align: center;">(Stamped)</div>
2. Signature 	3. Title Regulatory Label Specialist		
4. Typed Name Nancy Huebl	5. Date 07-Apr-99		



ZOECON



FOR USE ONLY IN  
THE STATE OF  
NEW YORK

# Altosid<sup>®</sup> XR

## EXTENDED RESIDUAL BRIQUETS

A SUSTAINED RELEASE PRODUCT TO PREVENT  
ADULT MOSQUITO EMERGENCE

ACTIVE INGREDIENT: (S)-Methoprene [Isopropyl(2E, 4E,  
7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:  
(Dry Weight Basis) .....2.1%  
OTHER INGREDIENTS: .....97.9%  
TOTAL: .....100.0%

This product contains water; therefore the weight of the briquet and per-  
cent by weight of active ingredient will vary with hydration. The ingredient  
statement is expressed on a dry weight basis.

KEEP OUT OF REACH OF CHILDREN

### CAUTION

NET WT 17.7 LBS (8kg) DRY WEIGHT BASIS  
CONTAINS 220 BRIQUETS

LOT NO.

BEST IF USED BY:

00670



00674

**INTRODUCTION:** ALTOSID® XR BRIQUETS are designed to release effective levels of Methoprene insect growth regulator over a period up to 150 days in mosquito breeding sites. Release of Methoprene insect growth regulator occurs by dissolution of the briquet. Soft mud and loose sediment can cover the briquets and inhibit normal dispersion of the active ingredient. The product may not be effective in those situations where the briquet can be removed from the site by flushing action.

ALTOSID XR BRIQUETS prevent the emergence of adult mosquitoes including *Anopheles*, *Culex*, *Culiseta*, *Coquillettidia*, and *Mansonia* spp. as well as those of the flood-water mosquito complex (*Aedes* and *Psorophora* spp.) from treated water. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** Methoprene insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

**PRECAUTIONS:** Do not apply to known fish habitat.

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**APPLICATION TIME:** Placement of ALTOSID XR BRIQUETS should be at or before the beginning of the mosquito season. ALTOSID XR BRIQUETS can be applied prior to flooding when sites are dry, or on snow and ice in breeding sites prior to spring thaw. Under normal conditions, one application should last the entire mosquito season, or up to 150 days, whichever is shorter. Alternate wetting and drying will not reduce their effectiveness.

**APPLICATION RATES:** *Aedes* and *Psorophora* spp.: For control in non-(or low-) flow shallow depressions (less than 2 feet in depth), treat on the basis of surface area, placing 1 briquet per 200 ft<sup>2</sup>. Briquets should be placed in the lowest areas of mosquito breeding sites to maintain continuous control as the site alternately floods and dries up.

*Culex*, *Culiseta* and *Anopheles* spp.: Place one ALTOSID XR BRIQUET per 100 ft<sup>2</sup>.

*Coquillettidia* and *Mansonia* spp.: For application to cattail marshes, and water hyacinth beds. For control of these mosquitoes, place one briquet per 100 ft<sup>2</sup>.

**APPLICATION SITES:** ALTOSID XR BRIQUETS are designed to control mosquitoes in small bodies of water which are not known fish habitats. Examples of application sites are: storm drains, catch basins, roadside ditches, ornamental ponds and fountains, cesspools and septic tanks, waste treatment settling ponds, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, cattail marshes, water-hyacinth beds, pastures, meadows, rice fields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, flood plains and dredging spoil sites. For application sites connected by a water system, i.e., storm drains or catch basins, all of the water-holding sites in the system should be treated to maximize the efficiency of the treatment program.

**Storage & Disposal:** **Storage:** Store in a cool place. Do not contaminate water, food or feed by storage or disposal. Do not reuse empty container. **Disposal:** Dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Warranty and Conditions of Sale:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information, or in case of an emergency, call 1-800-248-7763.

EPA Reg. No. 2724-421

EPA Est. No.: 39578-TX-1

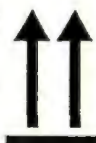
© 1999 Wellmark International

ALTOSID® XR Extended Residual Briquets and ZOECON® are registered trademarks of Wellmark International

Made in USA

**Wellmark**

Bensenville, Illinois 60106







United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-448	2. EPA Product Manager R. Sjoblad	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Zoecon RF-330 Altosid Pellets	PM # Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1000 Tower Lane Bensenville, Illinois 60106  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and section II.)

Notification of use of New York only label (containing fish habitat restriction in Environmental Hazards-not matching current EPA approved label) until such time as NY reviews/approves data package to remove the fish habitat restriction.

### Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 to 100 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Regulatory Label Specialist	Telephone No. (Include Area Code) (630) 227-6017
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
2. Signature 	3. Title Regulatory Label Specialist	
4. Typed Name Nancy Huebl	5. Date 07-Apr-99	

FOR USE ONLY IN THE  
STATE OF NEW YORK



# Altosid<sup>®</sup> PELLETS

## MOSQUITO GROWTH REGULATOR

### A GRANULAR PRODUCT TO PREVENT ADULT MOSQUITO EMERGENCE

ACTIVE INGREDIENT: (S) - Methoprene [Isopropyl (2E, 4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]: .... 4.25%  
OTHER INGREDIENTS: ..... 95.75%  
TOTAL: ..... 100.00%

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**

**NET WT 22 LBS (10 kg)**

#### PRECAUTIONARY STATEMENTS

##### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

##### ENVIRONMENTAL HAZARDS: Do not apply to known fish habitat.

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID<sup>®</sup> PELLETS release ALTOSID<sup>®</sup> Insect Growth Regulator as they erode. The pellets prevent the emergence of adult standing water mosquitoes, including *Culex* and *Coquidea* spp., as well as adults of the floodwater mosquitoes (*Aedes*, *Anopheles* and *Psorophora* spp.) from treated sites.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die. **NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

##### APPLICATION SITES AND RATES:

HABITAT	RATES (Lb/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5.0
Dredging spoil sites, waste treatment and settling ponds, ditches and other man-made depressions	5.0 - 10.0
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5.0
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste treatment settling ponds	5.0 - 10.0

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**Application Methods:** Apply ALTOSID PELLETS up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Flood wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID PELLETS. The pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID PELLETS may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. **Storage:** Store closed containers of ALTOSID PELLETS in a cool, dry place. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of the product other than indicated on the label. Buyer assumes all risks of use and handling of the material when such use and handling are contrary to label instructions.

For information, call: 1-800-248-7763.

**Wellmark**

Bensenville, Illinois 60106

EPA Reg. No. 2724-448

EPA Est. No. 39578-TX-1

©1999 Wellmark International

Made in USA

ALTOSID<sup>®</sup> Pellets, ALTOSID<sup>®</sup> Insect Growth Regulator and ZOECON<sup>®</sup> are registered trademarks of Wellmark International

Best if used by:

Lot No.

37775



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 29 1999

Mr. Steven R. Spaulding  
Wellmark International  
1000 Tower Lane  
Bensenville, Illinois 60106

Dear Mr. Spaulding:

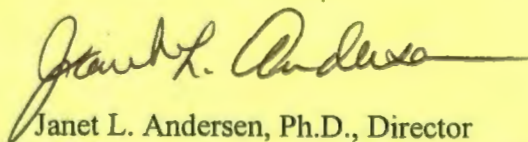
Subject: Wellmark International/Zoecon RF-330 Altosid Pellets  
EPA Reg. NO.: 2724-448  
Your submission of April 14, 1999

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended **IS ACCEPTABLE**. A stamped copy of the label is enclosed for your records.

**DESCRIPTION OF MAJOR LABEL CHANGES ACCEPTED**

1. Added nuisance pests/filter flies marketing claims  
Ingredient Statement: PRN-97-5 - dropped a.i. chemical name, added CAS#  
PRN-97-6 - changed "Inert" to "Other"  
Add Lot No.
2. Introduction: Additional marketing text for filter fly addition  
Directions for Use: Application Sites/Rates, Application Methods specific to waste water facilities/pests added
3. Storage and Disposal-added Pesticide Disposal and Container Disposal as headers
4. PRN 97- 4 - added information phone number
5. Added "registered" to trademark reference.

Sincerely,

  
Janet L. Andersen, Ph.D., Director  
Biopesticides and pollution Prevention  
Division(7511C)

Enclosure

CONCURRENCES			
SYMBOL	Wnelson:308-8682:EPA Reg. NO:2724-448:methoprene		
SURNAME	Rill		
DATE	7/29/99		



[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence  
[Prevents Nuisance Midge [Filter Fly] Emergence]  
[Controls waste water nuisance pests][filter flies]

**ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #65733-16-6) ..... 4.25%

**OTHER INGREDIENTS:** ..... 95.75%

Total ..... 100.00%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

EPA Reg. No. 2724-448

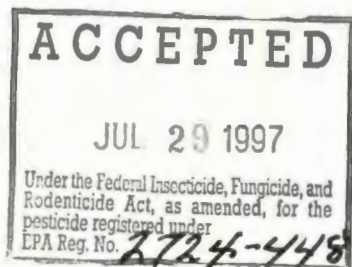
Best if used by:

Lot No.

NET WEIGHT:

EPA Est. No.

7/29/97 label  
accepted



**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**CAUTION**

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rinsate or equipment washwaters.

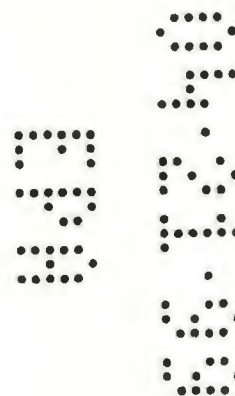
**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID®, an Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquillettidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes* and *Psorophora* spp. from treated sites. ALTOSID Pellets also control nuisance midge larvae.

**[INTRODUCTION:** ALTOSID® Pellets are a unique product that control filter flies (*Psychoda* spp.), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water facilities. ALTOSID Pellets contain an Insect Growth Regulator (IGR) that is effective on the developing stages of insect pests. ALTOSID Pellets do not kill adults but affects the larval stages as they grow and develop. ALTOSID Pellets stop the formation of pupa of insect pests, thereby eliminating adult populations. ALTOSID Pellets stop the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.]

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [midges][filter flies] which have reached the pupal or adult stage prior to treatment.



## APPLICATION SITES AND RATES:

Use lower application rates when water is shallow, vegetation and/or pollution are minimal, and insect populations are low. Use higher rates when water is deep (>2 ft), vegetation, pollution, and/or organic debris or water flow are high, and insect populations are high. [In instances of high organic debris and water flow, residual activity may be diminished.]

### MOSQUITO HABITAT

### RATES (Lb/Acre)

#### FLOODWATER SITES

Pastures, meadows, rice fields,  
freshwater swamps and marshes, salt and  
tidal marshes, cattail marshes, woodland pools,  
floodplains, tires, other artificial water-holding containers

2.5-5

Dredging spoil sites, waste treatment and settling  
ponds, ditches and other manmade depressions

5-10

#### PERMANENT WATER SITES

Ornamental ponds and fountains, fish ponds,  
cattail marshes, water hyacinth beds, flooded crypts,  
transformer vaults, abandoned swimming pools,  
construction and other manmade depressions,  
treeholes, other artificial water-holding containers

2.5-5

Storm drains, catch basins, roadside ditches,  
cesspools, septic tanks, waste settling ponds,  
vegetation-choked phosphate pits

5-10

### MIDGE HABITAT

### RATES (Lb/Acre)

Midge larvae occur in natural and manmade aquatic  
habitats, both permanent and temporary. Examples  
of these include ditches, streams and ponds, and  
natural and manmade lakes. Apply pellets uniformly  
to the water surface. Repeat application as necessary.

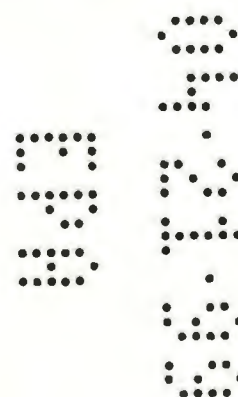
5-10

### FILTER FLY HABITAT

### RATES (Lb/Acre)

Filter flies and midges are waste water treatment pests inhabiting  
sludge drying beds, clarifiers, holding tanks or ponds,  
sewage lagoons, evisceration ponds, paper or food waste  
ponds, stagnant or standing water, or other areas of waste  
water treatment facilities where midges, filter flies, and other  
nuisance aquatic insect pests are a problem.

5-10





## APPLICATION METHODS

**Mosquitoes/Midges:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10 lb/acre may be used to apply ALTOSID Pellets. The pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

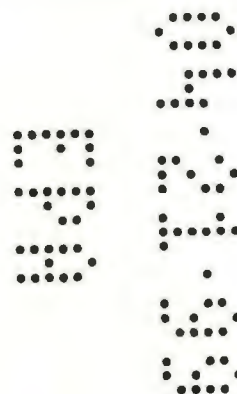
**[Waste Water Nuisance Pests:** For applications to solid waste, including sludge and retention ponds, the initial high rate of 10 lb/acre is recommended. Immediately following filling of the drying beds, application of the product should be made uniformly to the surface of the bed. Application of ALTOSID Pellets to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

For applications in aquatic habitats, including waste water treatment facilities, evisceration ponds, sewage lagoons, manure runoff areas, retention ponds, and holding tanks, apply ALTOSID Pellets as uniformly as possible over the entire surface. In situations where the ponds are large, applications made around the perimeter of the ponds can be helpful in reducing pests. In these situations, make applications up to a 20 foot band out from the bank around the pond perimeter.

ALTOSID Pellets may be applied by using suitable application equipment, such as, hand or motorized spreaders, backpack blowers, or aircraft (rotary or fixed wing). Even coverage over the surface of the area to be treated is critical for optimum performance.

**What to Expect in Waste Water Facilities:** Following initial applications of ALTOSID Pellets, a gradual reduction in the number of adult pests will be seen over approximately a one week period. Reduction in adult populations will be noticeable within a 2 week period following the application. Due to varying conditions or heavy infestations, the period to expect control may be longer. Since the mode of action of ALTOSID Pellets is to prevent adult emergence, existing adults and pupa present at the time of initial application will complete their life cycle.]

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. Store closed containers of ALTOSID Pellets in a cool dry place. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



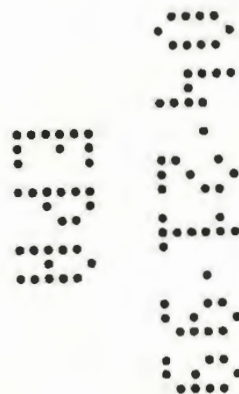
**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information or in case of an emergency, call [phone number].

ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are registered trademarks of Wellmark International.

Wellmark International  
Bensenville IL 60106

Made in USA



Label Review Sheet

**FILENAME:** g:\regulatory\LABELS\  
02724448\ar330ApA 99a

**COVERSHEET  
UPDATE:**

March 1999

**PRODUCT:** ZOECON RF-330  
ALTOSID PELLETS

**EPA REG. NO.:**

2724-448

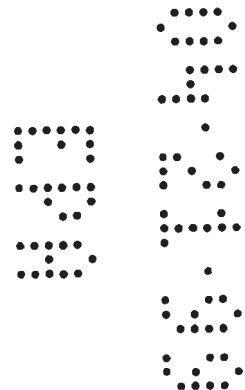
**APPROVED** Submitted 4/99

**SUPERSEDES:**

4/17/97

**OVERVIEW:** Notification submitted to add pest (filter flies) to existing site (waste water treatment areas) on label

Page #	Description of Major Changes
1	Added nuisance pests/filter flies marketing claims Ingredient Statement: PRN-97-5 – dropped ai chemical name, added CAS # PRN-97-6 – changed “Inert” to “Other” Added Lot No.
2	Introduction: Additional marketing text for filter fly addition
3-4	Directions for Use: Application Sites/Rates, Application Methods specific to waste water facilities/pests added
5	Storage and Disposal – added Pesticide Disposal and Container Disposal as headers PRN 97-4 – added information phone number Added “registered” to trademark reference





[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence  
[Prevents Nuisance Midge **[Filter Fly]** Emergence]  
**[Controls waste water nuisance pests][filter flies]**

**ACTIVE INGREDIENT:**

(S)-Methoprene [ <del>Isopropyl (2E,4E,7S)-</del> <del>11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]</del> (CAS #65733-16-6)	4.25%
<del>INERT-OTHER</del> INGREDIENTS:	95.75%
Total	100.00%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

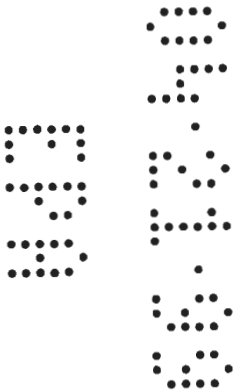
EPA Reg. No. 2724-448

EPA Est. No.

Best if used by:

**Lot No.**

NET WEIGHT:



**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**CAUTION**

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rinsate or equipment washwaters.

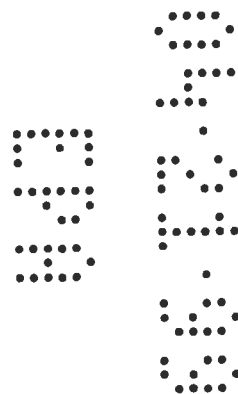
**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID®, [an] Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquilleltidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes* and *Psorophora* spp. from treated sites. ALTOSID Pellets also control nuisance midge larvae.

[**INTRODUCTION:** ALTOSID Pellets are a unique product that control filter flies (*Psychoda* spp.), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water facilities. ALTOSID Pellets contain an Insect Growth Regulator (IGR) that is effective on the developing stages of insect pests. ALTOSID Pellets do not kill adults but affects the larval stages as they grow and develop. ALTOSID Pellets stop the formation of pupa of insect pests, thereby eliminating adult populations. ALTOSID Pellets stop the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.]

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [midges][filter flies] which have reached the pupal or adult stage prior to treatment.



## APPLICATION SITES AND RATES:

Use lower **application** rates when water is shallow, vegetation and/or pollution are minimal, and **mosquito insect** populations are low. Use higher rates when water is deep (>2 ft), vegetation, and/or pollution, **and/or organic debris or water flow** are high, and **mosquito insect** populations are high. [In instances of high organic debris and water flow, residual activity may be diminished.]

### MOSQUITO HABITAT

### RATES (Lb/Acre)

#### FLOODWATER SITES

Pastures, meadows, rice fields,  
freshwater swamps and marshes, salt and  
tidal marshes, cattail marshes, woodland pools,  
floodplains, tires, other artificial water-holding containers

2.5-5

Dredging spoil sites, waste treatment and settling  
ponds, ditches and other manmade depressions

5-10

#### PERMANENT WATER SITES

Ornamental ponds and fountains, fish ponds,  
cattail marshes, water hyacinth beds, flooded crypts,  
transformer vaults, abandoned swimming pools,  
construction and other manmade depressions,  
treeholes, other artificial water-holding containers

2.5-5

Storm drains, catch basins, roadside ditches,  
cesspools, septic tanks, waste settling ponds,  
vegetation-choked phosphate pits

5-10

### MIDGE HABITAT

### RATES (Lb/Acre)

Midge larvae occur in natural and manmade aquatic  
habitats, both permanent and temporary. Examples  
of these include ditches, streams and ponds, and  
natural and manmade lakes. Apply pellets uniformly  
to the water surface. Repeat application as necessary.

5-10

### FILTER FLY HABITAT

### RATES (Lb/Acre)

Filter flies and midges are waste water treatment pests inhabiting  
sludge drying beds, clarifiers, holding tanks or ponds,  
sewage lagoons, evisceration ponds, paper or food waste  
ponds, stagnant or standing water, or other areas of waste  
water treatment facilities where midges, filter flies, and other  
nuisance aquatic insect pests are a problem.

5-10

~~Use lower rates when water is shallow, vegetation and/or pollution are minimal, and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high, and mosquito populations are high.~~



## APPLICATION METHODS

**Mosquitoes/Midges:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10 lb/acre may be used to apply ALTOSID Pellets. The pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

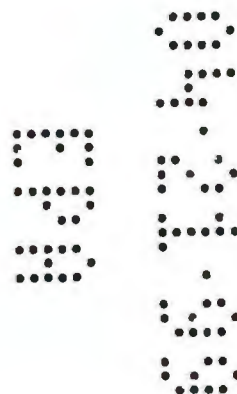
**[Waste Water Nuisance Pests:** For applications to solid waste, including sludge and retention ponds, the initial high rate of 10 lb/acre is recommended. Immediately following filling of the drying beds, application of the product should be made uniformly to the surface of the bed. Application of ALTOSID Pellets to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

For applications in aquatic habitats, including waste water treatment facilities, evisceration ponds, sewage lagoons, manure runoff areas, retention ponds, and holding tanks, apply ALTOSID Pellets as uniformly as possible over the entire surface. In situations where the ponds are large, applications made around the perimeter of the ponds can be helpful in reducing pests. In these situations, make applications up to a 20 foot band out from the bank around the pond perimeter.

ALTOSID Pellets may be applied by using suitable application equipment, such as, hand or motorized spreaders, backpack blowers, or aircraft (rotary or fixed wing). Even coverage over the surface of the area to be treated is critical for optimum performance.

**What to Expect in Waste Water Facilities:** Following initial applications of ALTOSID Pellets, a gradual reduction in the number of adult pests will be seen over approximately a one week period. Reduction in adult populations will be noticeable within a 2 week period following the application. Due to varying conditions or heavy infestations, the period to expect control may be longer. Since the mode of action of ALTOSID Pellets is to prevent adult emergence, existing adults and pupa present at the time of initial application will complete their life cycle.]

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. Store closed containers of ALTOSID Pellets in a cool dry place. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.



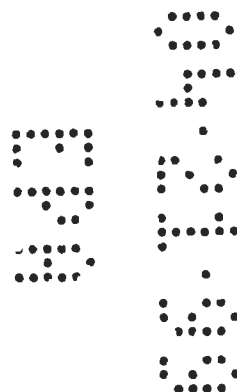
**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information or in case of an emergency, call [phone number].

ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are registered trademarks of Wellmark International.

Wellmark International  
Bensenville IL 60106

Made in USA





April 16, 1999

Document Processing Desk (NOTIF)  
Office of Pesticide Programs - H7504C  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Attn: Mr. Willie Nelson  
Biopesticides and Pollution Prevention Division

**Subject: Zoecon RF-330 Altosid Pellets  
(EPA Reg. No. 2724-448)  
Notification to Add New Pest Species to Label**

The purpose of this notification is to add filter flies (sometimes referred to as moth flies; *Psychoda* spp.) to the Zoecon RF-330 Altosid Pellets label. Altosid Pellets contain 4.25% (S)-Methoprene and the current label includes claims to control mosquito and midge populations. Filter flies are a serious nuisance pest infesting wastewater facilities and nearby areas and few effective control agents are available. This pest does not represent a new use for our methoprene product line since filter flies were previously added by notification to the liquid RF-437 Mosquito Growth Regulator label (EPA Reg. No. 2724-446) in August 1997. By adding filter flies to the solid methoprene pellet label, we will provide our customers with both solid and liquid methoprene formulations to meet their pest control needs.

This submission complies with PR-Notice 98-10 criteria for notifications to add a pest to the label for the following reasons:

1. Filter flies are not considered public health pests therefore efficacy data has not been submitted with this notification; however, data are on file with Wellmark to support the addition of this pest species to the label.
2. The current approved label already includes waste treatment and settling ponds as approved application sites and these are the same areas where Altosid Pellets will be applied to control filter flies. The enclosed label includes expanded language to clarify applications to wastewater areas.
3. Filter flies match the type of product registered (ie; insect growth regulator as opposed to fungicide, herbicide, etc.).
4. The dosage, frequency, concentration and method of application are the same for nuisance wastewater pests and those currently approved for mosquitoes and midges on the Altosid Pellet label. Treatment of filter flies in wastewater facilities as well as mosquitoes and midges in standing water requires application of pellets directly to the site at 5-10 lbs./acre.



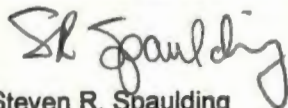
5. Addition of the pest does not significantly increase exposure of the pesticide to humans or the environment.
6. Filter flies are not subject to quarantine.

Enclosed with this notification is an Application for Pesticide Registration Form 8570-1 and 1 copy of the revised label with the changes clearly marked in red to aid in the review and 1 unmarked copy of the revised label with the changes incorporated. Please return a stamped - approved copy of the unmarked revised label so that we may initiate state registrations of this product.

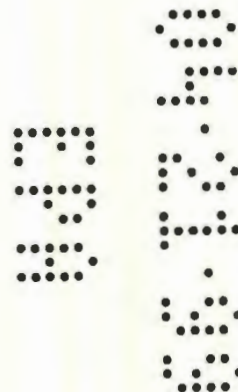
Please contact me at 630/227-6074 if you have any questions concerning this notification.

Sincerely,

**WELLMARK INTERNATIONAL**



Steven R. Spaulding  
Manager, Regulatory Affairs

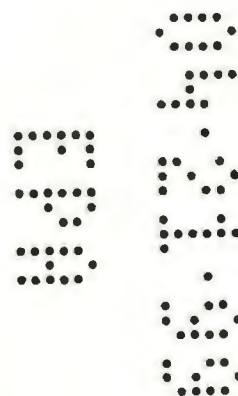


# Label Review Sheet

<b>FILENAME:</b>	g:\regulatory\LABELS\ 02724448\ar330ApA 99a	<b>COVERSHEET UPDATE:</b>	March 1999
<b>PRODUCT:</b>	ZOECON RF-330 ALTOSID PELLETS	<b>EPA REG. NO.:</b>	2724-448
<b>APPROVED:</b>	Submitted 4/99	<b>SUPERSEDES:</b>	4/17/97

**OVERVIEW:** Notification submitted to add pest (filter flies) to existing site (waste water treatment areas) on label

Page #	Description of Major Changes
1	Added nuisance pests/filter flies marketing claims Ingredient Statement: PRN-97-5 – dropped ai chemical name, added CAS # PRN-97-6 – changed "Inert" to "Other" Added Lot No.
2	Introduction: Additional marketing text for filter fly addition
3-4	Directions for Use: Application Sites/Rates, Application Methods specific to waste water facilities/pests added
5	Storage and Disposal – added Pesticide Disposal and Container Disposal as headers PRN 97-4 – added information phone number Added "registered" to trademark reference





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-448	2. EPA Product Manager R. Sjoblad	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Zoecon RF-330 Altosid Pellets	PM # 91 Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1000 Tower Lane Bensenville, Illinois 60106  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and section II.)

Notification to add pest (filter flies) to existing site (waste water treatment areas) on label

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

1. Material This Product Will be Packaged In:			2. Type of Container	
Child-Resistant Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
Certification must be submitted If "Yes" Unit Packaging wgt. No. per container		If "Yes" Unit Packaging wgt. No. per container		
3. Location of Net Contents Information  <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 to 100 lbs		5. Location of Label Directions  <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Steven R. Spaulding	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (630) 227-6074
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, Regulatory Affairs	
4. Typed Name Steven R. Spaulding	5. Date April 14, 1999	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 15 1999

Ms. Cathy Elmi  
Wellmark International  
Regulatory Affairs  
1000 Tower Lane  
Suite 245  
Bensenville, IL 60106

Dear Ms. Elmi:

Subject: Modification of Wellmark International's Altosid Solid Formulations (2724-448, 2724-375 and 2724-421) Fish Habitat Labeling Restriction Reinstatement

Thank you for your fax to Mr. Willie H. Nelson dated March 24, 1999, requesting a specific restriction for labeling to be used in New York to read, in the upper left hand corner of the front panel of your Altosid products labeling to state **"FOR USE ONLY IN THE STATE OF NEW YORK"** and to allow for the reinstatement, under the Environmental hazards Statement, **"Do not apply to known fish habitats"** to be added back onto the label. The request **IS HEREBY GRANTED** for one year from the stamped date of this letter.

Should you have any questions concerning this letter, please feel free to contact Mr. Willie H. Nelson at (703) 308-8682.

Sincerely,

Janet L. Andersen, Ph.D., Director  
Biopesticides and Pollution Prevention  
Division(7511C)

CONCURRENCES							
SYMBOL	Wnelson:308-8682:2724-448,375 and 421:methoprene:04/14/99						
SURNAME							
DATE							

**FAX**

**Wellmark International**  
Regulatory Affairs  
1000 Tower Lane  
Suite 245  
Bensenville, IL 60106

**Wellmark**

<b>To:</b> Mr. Willie Nelson <b>Tel:</b> <b>FAX:</b> 703/308-7026	<b>cc:</b>  <b>File:</b>
<b>From:</b> Cathy Elmi <b>Tel:</b> (630)227-6016 <b>FAX:</b> (630)227-6065 <b>Pages:</b> 5 (including cover page)	<b>Date:</b> March 24, 1999
If you do not receive all pages of this fax, please call 630.227.6016	

**SUBJECT:** Altosid Solid Formulations (2724-448, 2724-375 and 2724-421)  
Fish Habitat Restriction Removal

Dear Ms. Nelson:

In October 1996 the EPA approved the removal of the fish habitat restriction from the subject three solid formulations. Sandoz proceeded to update their labeling with the revised Environmental Hazards Statement "This product is toxic to aquatic dipteran..." as stated in EPA's 10/31/96 letter.

Unfortunately, this removal of the fish habitat restriction has not been approved by the state of New York. This revision according to their regulations is a major new use to these labels and will require all data, correspondence and EPA reviews before they will approve this label revision.

Therefore, Wellmark has been using the old Sandoz labeled inventory, which still had the "Do not apply to known fish habitats" for sale in New York. As you know according to the June 23, 1997 EPA transfer letter from Sandoz to Wellmark we had until 12/23/98 to ship Sandoz labeled inventory. Therefore, we no longer can ship the Sandoz label with the restriction.

In order to maintain sales I have submitted for registration in New York a "New York only" label, which is identical to the current WELLMARK EPA, stamped approved with the following exceptions (see attached label):

1. In the upper left hand corner of the front panel it states "FOR USE ONLY IN THE STATE OF NEW YORK"

Page 2

2. Under the Environmental Hazards Statement "Do not apply to known fish habitats" was added back into the label where as the current EPA stamped approved does not include this statement.

New York was agreeable to registering a New York only label but was concerned with the Environmental Hazards statement not matching the current EPA stamped approved label. They requested we ask whether EPA would need a notification that these three labels are being created for New York only and the Environmental Hazards statement will reflect the former EPA stamped approved "Do not apply to known fish habitats" rather than the current EPA approved "this product is toxic to aquatic dipteran...". This would be a temporary solution until the data and all correspondence are submitted to New York and reviewed.

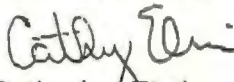
Do we need to submit a notification to EPA for these New York only labels or is the EPA comfortable with New York's approval of these labels even though the Environmental Hazards statement reflects a former EPA stamped approved label?

If you should have any questions, please contact me at 630/227-6016 or Nancy Huebl at 630/227-6017. Or if you need to discuss this with New York directly you can contact Mr. Frank Hegener, NY DEC at 518/457-7446.

Thank you for your assistance with this issue.

Sincerely,

**WELLMARK INTERNATIONAL**



Catherine Elmi  
State Regulatory Manager

Enclosure



Proposed New York  
only label

FOR USE ONLY IN THE  
STATE OF NEW YORK



# Altosid<sup>®</sup> PELLETS

## MOSQUITO GROWTH REGULATOR

### A GRANULAR PRODUCT TO PREVENT ADULT MOSQUITO EMERGENCE

ACTIVE INGREDIENT: (S) - Methoprene [Isopropyl (2E, 4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]: . . . 4.25%  
OTHER INGREDIENTS: . . . 95.75%  
TOTAL: . . . 100.00%

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**

NET WT 22 LBS (10 kg)

#### PRECAUTIONARY STATEMENTS

##### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

ENVIRONMENTAL HAZARDS: Do not apply to known fish habitat.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INTRODUCTION: ALTOSID<sup>®</sup> PELLETS release ALTOSID<sup>®</sup> Insect Growth Regulator as they erode. The pellets prevent the emergence of adult standing water mosquitoes, including *Culex* and *Culiseta* spp., as well as adults of the floodwater mosquitoes (*Aedes*, *Anopheles* and *Psorophora* spp.) from treated sites.

GENERAL DIRECTIONS: ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die. NOTE: This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

##### APPLICATION SITES AND RATES:

HABITAT	RATES (lb/acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5.0
Uredging spoil sites, waste treatment and settling ponds, ditches and other manmade depressions	5.0 - 10.0
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5.0
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste treatment settling ponds	5.0 - 10.0

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

Application Methods: Apply ALTOSID PELLETS up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID PELLETS. The pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID PELLETS may be applied to artificial containers such as tires and catch basins, etc.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Storage: Store closed containers of ALTOSID PELLETS in a cool, dry place. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND CONDITIONS OF SALE: Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information, call: 1-800-248-7763.

**Wellmark**

Benzenville, Illinois 60106

ALTOSID<sup>®</sup> Pellets, ALTOSID<sup>®</sup> Insect Growth Regulator and ZOECON<sup>®</sup> are registered trademarks of Wellmark International

Best if used by:

Lot No.

37775

EPA Reg. No. 2724-448  
EPA Est. No. 39578-1X-1  
©1999 Wellmark International  
Made in USA

current EPA approved  
Wellmark label



# Altosid<sup>®</sup> PELLETS

## MOSQUITO GROWTH REGULATOR

**A GRANULAR PRODUCT TO PREVENT ADULT MOSQUITO OR MIDGE EMERGENCE**

**ACTIVE INGREDIENT: (S) - Methoprene [isopropyl 2E, 4E, 7S]-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]: . . . . 4.25%**  
**OTHER INGREDIENTS: . . . . . 95.75%**  
**TOTAL: . . . . . 100.00%**

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**  
**NET WT 22 LBS (10 kg)**

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rinsate or equipment washwaters.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID<sup>®</sup> Pellets release ALTOSID<sup>®</sup> Insect Growth Regulator as they erode. The pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Quixote*, *Coquillettidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes* and *Psorophora* spp. from treated sites. ALTOSID Pellets also control nuisance midge larvae.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes or midges which have reached the pupal or adult stage prior to treatment.

#### APPLICATION SITES AND RATES:

MOSQUITO HABITAT	RATES (Lb/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, cattail marshes, woodland pools, floodplains, tires, other artificial water-holding containers	2.5 - 5.0
Dredging spoil sites, waste treatment and settling ponds, ditches and other manmade depressions	5.0 - 10.0
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, fish ponds, cattail marshes, water hyacinth beds, flooded crypts, transformer vaults, abandoned swimming pools, construction and other manmade depressions, treeholes, other artificial water-holding containers	2.5 - 5.0
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds, vegetation-choked phosphate pits	5.0 - 10.0

#### MIDGE HABITAT

#### RATES (Lb/Acre)

Midge larvae occur in natural and manmade aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds, and natural and manmade lakes. Apply pellets uniformly to the water surface. Repeat application as necessary.

5.0 - 10.0

Use lower rates when water is shallow, vegetation and/or pollution are minimal, and mosquito/midge populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high, and mosquito/midge populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding, or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10.0 lb/acre may be used to apply ALTOSID Pellets. The pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. Storage: Store closed containers of ALTOSID Pellets in a cool, dry place. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information, call: 1-800-248-7763.

**Wellmark**

Bensenville, Illinois 60106

EPA Reg. No. 2724-448

EPA Est. No. 39578-TX-1

©1998 Wellmark International  
Made in USA

ALTOSID<sup>®</sup> Pellets, ALTOSID<sup>®</sup> Insect Growth Regulator, and ZOECON<sup>®</sup> are registered trademarks of Wellmark International

Best if used by:

Lot No.

033250

SLD



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 31 1996

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Mr. Steven Spaulding  
Sandoz Agro, Inc.  
1300 E. Touhy Avenue  
Des Plaines, Illinois 60018

Dear Mr. Spaulding:

Subject: Altosid Briquets  
EPA Reg. No. 2724-375  
Your submission between 1993-1996 in support of the  
removal of the fish habitat labeling precaution  
statement

The amendment referred to above, submitted in connection  
with registration under FIFRA sec. 3(c)(7)(A) requesting:

1. Removal of the statement "Do not use in fish-bearing  
waters", and
2. Modification of the labeling required statement "This  
product is toxic to aquatic invertebrates" to read, "This product  
is toxic to aquatic dipteran" is acceptable provided that you:
  1. Submit and/or cite all data required for  
registration/reregistration of your product under FIFRA sec.  
3(c)(5) when the Agency requires all registrants of similar  
products to submit such data.
  2. Submit five (5) copies of the corrected final printed  
labeling.

If these conditions are not complied with, the registration  
will be subject to cancellation in accordance with FIFRA sec.  
6(e). Your release for shipment of the product constitutes  
acceptance of these conditions

*Received this same letter  
for all solid formulations (-375, -421, -448)*



# BPPD PRAT ACTION CODING FORM

PM 90: Janet Anderson

REVIEWER: Willie Nelson

(ASSIGNED BY: SKR)

EPA REG./FILE SYMBOL 2724-448

ACTION CODE 332

SUBMISSION BARCODE S564976

Date on Application

5/20/99

EPA Received Date

5/24/99

PM Received Date

6/18/99

Assigned in PRAT YES X

NO     

Completed by: sdh

Date 7/7/99

NOTIFICATION

## FINAL ACTION

Response Code     

Response Date:      /      /     

MOS:      (1) Cite All

     (4) Not Applicable

     (8) Selective

CRP: Yes      No     

Restricted Use: Yes      No     

Manufacturing Use: Yes      No     

Exclusive Use: Yes      No

2724-448

Notification: ~~PRN 98-10~~ Alternate Brand Name

Wellmark International

Nancy Huebl  
630-227-6017

160



*Nancy Huebl*  
WELLMARK INTERNATIONAL  
1000 TOWER LANE SUITE 245  
BENSENVILLE IL 60106

161



Wellmark International  
1000 Tower Lane, Suite 245  
Bensenville, Illinois 60106  
630 227 6000



May 20, 1999

Document Processing Desk (NOTIF)  
Office of Pesticide Programs H7504C  
U.S. Environmental Protection Agency  
Room 266A Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202

ATTENTION: S. Reilly

SUBJECT: NOTIFICATION OF LABEL REVISION PER PRN 98-10  
ZOËCON® RF-330 ALTOSID® PELLETS/EPA REG. NO. 2724-448

Dear Ms. Reilly:

Enclosed is completed EPA Form 8570-1 to serve as notification of the alternate brand name:  
STRIKE® Pellets.

If you have any questions, please, call me directly at 630/227-6017. Thank you for your assistance in  
this matter.

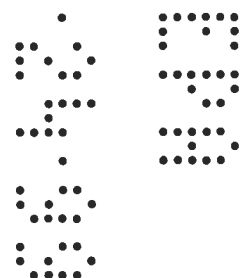
Yours sincerely,  
WELLMARK INTERNATIONAL

A handwritten signature in blue ink that reads "Nancy Huebl".

Nancy Huebl  
Regulatory Label Specialist

enclosure

cc: S. Spaulding/C. Elmi/J. Richardson/J. Neberz





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-448	2. EPA Product Manager S. Reilly <i>R. S. Jobl</i>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/Zoecon RF-330 Altosid Pellets	PM # <i>91</i> Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1000 Tower Lane Bensenville, Illinois 60106  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and section II.)

Notification of alternate brand name: **STRIKE Pellets**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

1. Material This Product Will be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Unit Packaging wgt.	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 22 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____					

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Regulatory Label Specialist	Telephone No. (Include Area Code) (630) 227-6017
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received 
2. Signature <i>Nancy Huebl</i>	3. Title Regulatory Label Specialist	
4. Typed Name Nancy Huebl	5. Date May 20, 1999	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 23 1997

Mr. Steven R. Spaulding  
Wellmark International  
1000 Tower Lane, Suite 245  
Bensenville, IL 60106

Dear Mr. Spaulding:

Subject: **METHOPRENE REREGISTRATION**  
**Label Submitted for Methoprene reregistration Changes**  
**Zoecon RF-330 Altosid Pellets**  
**EPA REG. NO. 2724-448**  
**Your submission of September 4, 1997**

The amendment referred to above, submitted in connection with reregistration under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. **A stamped copy of the labeling is enclosed for your records.**

Sincerely,

*Janet L. Andersen*

Janet L. Andersen, Ph. D., Director  
Biopesticides and Pollution Prevention  
Division (7511W)

Wnelson:09/17/97:308-8682:epa no.2724-448:methoprene STD

CONCURRENCES

SYMBOL	7511W	7511W					
SURNAME	NE/SDR	NE/SDR					
DATE	9/23/97	9/23/97					



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 23 1997

SEP 23 1997

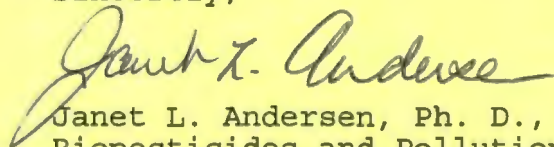
Mr. Steven R. Spaulding  
Wellmark International  
1000 Tower Lane, Suite 245  
Bensenville, IL 60106

Dear Mr. Spaulding:

Subject: **METHOPRENE REREGISTRATION**  
**Label Submitted for Methoprene reregistration Changes**  
**Zoecon RF-330 Altosid Pellets**  
**EPA REG. NO. 2724-448**  
**Your submission of September 4, 1997**

The amendment referred to above, submitted in connection with reregistration under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. **A stamped copy of the labeling is enclosed for your records.**

Sincerely,



Janet L. Andersen, Ph. D., Director  
Biopesticides and Pollution Prevention  
Division (7511W)

Wnelson:09/17/97:308-8682:epa no.2724-448:methoprene STD

CONCURRENCES							
SYMBOL	7511W	7511W					
SURNAME	Nelson	Porter					
DATE	9/23/97	9/23/97					

**METHOPRENE REREGISTRATION PRODUCT OVERVIEW**

September 5, 1997

PRODUCT	STAMPED LABEL	NOMINAL*	PRN 96-6	NAME CHANGE	CSF
2724-393 Altosid Liquid Larvicide Concentrate	Last stamped label 3/15/85 Need stamped label	Yes	NA	Submit 9/97	9/97
2724-421 Zoecon RF-292 Briquet	Rereg. letter 4/17/97 Need stamped label	Yes	NA	Submit 9/97	9/97
2724-446 Zoecon RF-437 Mosquito Growth Regulator SR-20 (Notification moth fly submitted 8/26/97)	Rereg. letter 4/17/97 Need stamped label	Yes	NA	Submit 9/97	9/97
2724-448 Zoecon RF-330 Altosid Pellets	Rereg. letter 4/17/97 Need stamped label	Yes	NA	Submit 9/97	9/97
2724-451 Altosid 9010 GR (Granules)	Rereg. letter 4/17/97	1.4% to 1.5% 9/97 CSF	NA	Submit 9/97	9/97
55947-158 <b>NEW: 2724-483</b> <b>Sandoz</b> 9404 Spray (Change in registration number)	Rereg. letter 5/13/97	Yes	Submit 9/97	Submit 9/97	9/97
<b>Reregistration - First Submission</b>					
2724-352 Zoecon RF-291 Emulsifiable Concentrate	Last stamped label 4/1989	1.0% to 1.2% 9/97	NA	Submit 9/97	9/97
2724-356 Zoecon RF-293 Methoprene Bolus (Caplet) Beef and Dairy Cattle	last stamped label 10/20/89	Yes	NA	Submit 9/97	9/97
2724-367 Zoecon Altosid CP-10 (RS)	last stamped label '78	10% to 10.5% 9/97	NA	Submit 9/97	9/97
2724-372 Zoecon Granular IGR Cattle Supplement (RS)	last stamped label 12/13/96	Yes	NA	Submit 9/97	9/97
2724-373 Zoecon Block IGR Cattle Supplement (RS)	last stamped label 10/27/77	Yes	NA	Submit 9/97	9/97
2724-377 Kabat Tobacco Protector (RS)	last stamped label 1/22/90	5.0% to 5.2% 9/97	NA	Submit 9/97	9/97
2724-384 Kabat Tobacco Protector Concentrate (RS)	last stamped label 9/19/80	Yes	NA	Submit 9/97	9/97

\* Values shown represent a change to nominal concentration for methoprene ai. Changes to other ai's are noted by name or abbreviation (PBO, permethrin)





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

257347

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-448	2. EPA Product Manager J. Anderson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/ Zoecon RF-330 Altosid Pellets	PM# 90	
5. Name and Address of Applicant (Include ZIP Code) Wellmark International 1000 Tower Lane Suite 245 Bensenville, IL 60106  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for reregistration

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input checked="" type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 to 100 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Steven R. Spaulding	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) 630-227-6074
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, Regulatory Affairs	
4. Typed Name Steven R. Spaulding	5. Date September 4, 1997	



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.





SANDOZ AGRO, Inc. - Label Review Sheet

FILENAME: N:\CENTGARD\LABELS\ 02724448\PRF330AA.97B      COVERSHEET      August 1997  
UPDATE:  
PRODUCT: ZOECON RF-330      EPA REG. NO.:      2724-448  
ALTOSID PELLETS  
APPROVED      SUPERSEDES:      4/17/97  
:

OVERVIEW: Label submitted for reregistration, name/address change Sandoz to Wellmark

Page #	Description of Major Changes
1	Patent reference removed - no longer valid
2	Added HAZARDS TO HUMANS... and signal word Environmental Hazards - typo corrected (rancid to rinsate)
4	Trademark sentence changed Sandoz to Wellmark Name/address changed Sandoz to Wellmark



[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence

[Prevents Nuisance Midge Emergence]

**ACTIVE INGREDIENT:**

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:\*..... 4.25%

**INERT INGREDIENTS:** ..... 95.75%

**Total:**..... 100.0%

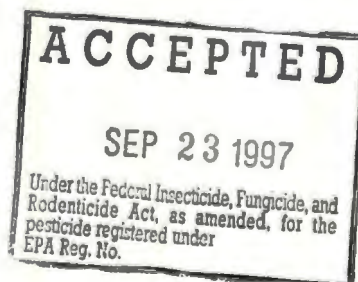
\_\_\_\_\_\*U.S. Patents: 3,904,662 and 3,912,815

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**Best if used by:**

**NET WEIGHT:**



## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of ~~rinser~~acid or equipment washwaters.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID® Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquillettidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes* and *Psorophora* spp. from treated sites. ALTOSID Pellets also controls nuisance midge larvae.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [or midges] which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

### MOSQUITO HABITAT

### RATES (Lb/Acre)

#### FLOODWATER SITES

Pastures, meadows, ricefields,  
freshwater swamps and marshes, salt and  
tidal marshes, cattail marshes, woodland pools,  
floodplains, tires, other artificial water-holding containers

2.5-5

Dredging spoil sites, waste treatment and settling  
ponds, ditches and other manmade depressions

5-10

#### PERMANENT WATER SITES

Ornamental ponds and fountains, fish ponds,  
cattail marshes, water hyacinth beds, flooded crypts,  
transformer vaults, abandoned swimming pools,  
construction and other manmade depressions,  
treeholes, other artificial water-holding containers

2.5-5

Storm drains, catch basins, roadside ditches,  
cesspools, septic tanks, waste settling ponds,  
vegetation-choked phosphate pits

5-10

### MIDGE HABITAT

### RATES (Lb/Acre)

Midge larvae occur in natural and manmade aquatic  
habitats, both permanent and temporary. Examples  
of these include ditches, streams and ponds and  
natural and manmade lakes. Apply pellets uniformly  
to the water surface. Repeat application as necessary.

5-10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito  
populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are  
high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any  
stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or  
helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10 lb/acre may  
be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment  
which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to  
artificial containers such as tires and catch basins, etc.



**STORAGE AND DISPOSAL:** Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are trademarks of **Wellmark International** ~~Sandoz Ltd.~~

**Wellmark International**  
**Bensenville IL 60106**  
**Sandoz Agro, Inc.**  
**1300 East Touhy Avenue**  
**Des Plaines, IL 60018**

EPA Reg. No.: 2724-448

EPA Est. No.:  
Made in USA

[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence

[Prevents Nuisance Midge Emergence]

**ACTIVE INGREDIENT:**

(S)-Methoprene [Isopropyl (2E,4E,7S)-

11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:..... 4.25%

**INERT INGREDIENTS:**..... 95.75%

**Total:**..... 100.0%

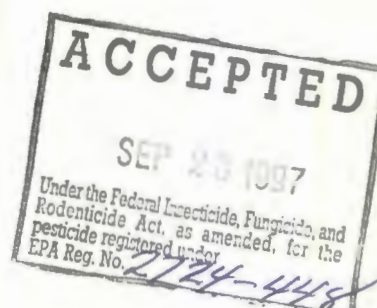
**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**Best if used by:**

**NET WEIGHT:**

9-23-97 label  
accepted



**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**CAUTION**

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rinsate or equipment washwaters.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID® Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquilleltidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes* and *Psorophora* spp. from treated sites. ALTOSID Pellets also controls nuisance midge larvae.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [or midges] which have reached the pupal or adult stage prior to treatment.



## APPLICATION SITES AND RATES:

<b>MOSQUITO HABITAT</b>	<b>RATES (Lb/Acre)</b>
<b><u>FLOODWATER SITES</u></b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, cattail marshes, woodland pools, floodplains, tires, other artificial water-holding containers	2.5-5
Dredging spoil sites, waste treatment and settling ponds, ditches and other manmade depressions	5-10
<b><u>PERMANENT WATER SITES</u></b>	
Ornamental ponds and fountains, fish ponds, cattail marshes, water hyacinth beds, flooded crypts, transformer vaults, abandoned swimming pools, construction and other manmade depressions, treeholes, other artificial water-holding containers	2.5-5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds, vegetation-choked phosphate pits	5-10
<b><u>MIDGE HABITAT</u></b>	<b>RATES (Lb/Acre)</b>
Midge larvae occur in natural and manmade aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds and natural and manmade lakes. Apply pellets uniformly to the water surface. Repeat application as necessary.	5-10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10 lb/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are trademarks of Wellmark International.

Wellmark International  
Bensenville IL 60106

EPA Reg. No.: 2724-448

EPA Est. No.:  
Made in USA

[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence

[Prevents Nuisance Midge Emergence]

**ACTIVE INGREDIENT:**

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]: ..... 4.25%

**INERT INGREDIENTS:** ..... 95.75%

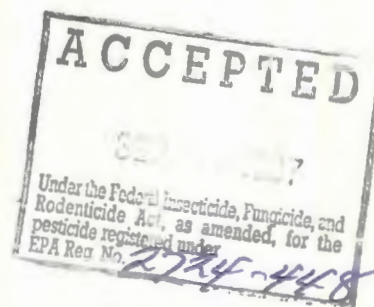
**Total:** ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**Best if used by:**

**NET WEIGHT:**





**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**CAUTION**

**ENVIROMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chronomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rinsate or equipment washwaters.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID® Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquillettidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes* and *Psorophora* spp. from treated sites. ALTOSID Pellets also controls nuisance midge larvae.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [or midges] which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

MOSQUITO HABITAT	RATES (Lb/Acre)
<b><u>FLOODWATER SITES</u></b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, cattail marshes, woodland pools, floodplains, tires, other artificial water-holding containers	2.5-5
Dredging spoil sites, waste treatment and settling ponds, ditches and other manmade depressions	5-10
<b><u>PERMANENT WATER SITES</u></b>	
Ornamental ponds and fountains, fish ponds, cattail marshes, water hyacinth beds, flooded crypts, transformer vaults, abandoned swimming pools, construction and other manmade depressions, treeholes, other artificial water-holding containers	2.5-5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds, vegetation-choked phosphate pits	5-10

MIDGE HABITAT	RATES (Lb/Acre)
Midge larvae occur in natural and manmade aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds and natural and manmade lakes. Apply pellets uniformly to the water surface. Repeat application as necessary.	5-10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10 lb/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are trademarks of Wellmark International.

Wellmark International  
Bensenville IL 60106

EPA Reg. No.: 2724-448

EPA Est. No.:  
Made in USA



[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence

[Prevents Nuisance Midge Emergence]

**ACTIVE INGREDIENT:**

(S)-Methoprene [Isopropyl (2E,4E,7S)-

11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:..... 4.25%

**INERT INGREDIENTS:**..... 95.75%

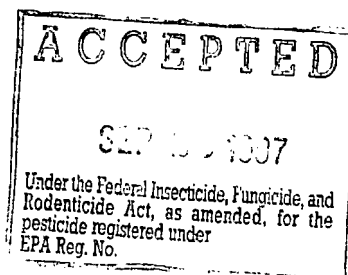
**Total:**..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**Best if used by:**

**NET WEIGHT:**



**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**CAUTION**

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rinsate or equipment washwaters.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID® Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquillettidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes* and *Psorophora* spp. from treated sites. ALTOSID Pellets also controls nuisance midge larvae.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [or midges] which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

### MOSQUITO HABITAT

### RATES (Lb/Acre)

#### FLOODWATER SITES

Pastures, meadows, ricefields,  
freshwater swamps and marshes, salt and  
tidal marshes, cattail marshes, woodland pools,  
floodplains, tires, other artificial water-holding containers

2.5-5

Dredging spoil sites, waste treatment and settling  
ponds, ditches and other manmade depressions

5-10

#### PERMANENT WATER SITES

Ornamental ponds and fountains, fish ponds,  
cattail marshes, water hyacinth beds, flooded crypts,  
transformer vaults, abandoned swimming pools,  
construction and other manmade depressions,  
treeholes, other artificial water-holding containers

2.5-5

Storm drains, catch basins, roadside ditches,  
cesspools, septic tanks, waste settling ponds,  
vegetation-choked phosphate pits

5-10

### MIDGE HABITAT

### RATES (Lb/Acre)

Midge larvae occur in natural and manmade aquatic  
habitats, both permanent and temporary. Examples  
of these include ditches, streams and ponds and  
natural and manmade lakes. Apply pellets uniformly  
to the water surface. Repeat application as necessary.

5-10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10 lb/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.



**STORAGE AND DISPOSAL:** Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are trademarks of Wellmark International.

Wellmark International  
Bensenville IL 60106

EPA Reg. No.: 2724-448

EPA Est. No.:  
Made in USA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

I, Roy Sjoblad, Branch Chief, Biochemical Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Prevention, Pesticide Toxic Substances certify that the pesticide product listed below is currently registered with the Agency under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, that the label attached is a true, and correct copy of the label accepted by the Agency, and that the product may be sold and marketed in the United States of America for the uses indicated on the label.

The product registration listed below has been issued to:

Wellmark International  
1000 Tower Lane, Suite 245  
Bensenville, Illinois 60106

EPA REGISTRATION NUMBER

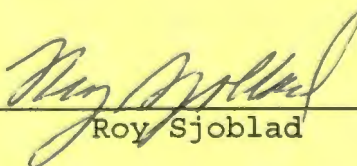
Altosid Liquid Larvicide  
Zoecon RF-437 Mosquito Growth Regulator SR 20  
Zoecon RF-292 Briquets  
Zoecon RF-330 Altosid Pellets Mosquito Growth  
Regulator  
Zoecon 9010 GR

PRODUCT NAME

2724-392  
2724-446  
2724-421  
2724-448 ✓  
2724-451

IN WITNESS WHEREOF

I have hereunto set my hand  
and affixed the seal of the  
U.S. Environmental Protection  
Agency this 24th day of July  
A.D. 1997

  
\_\_\_\_\_  
Roy Sjoblad

CONCURRENCES

SYMBOL	7501W	7501W	7501W					
SURNAME	Greedy	Nelson	Sjoblad					
DATE	7/22/97	7/24/97	7/24/97					

# BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

2724-392 ✓  
2724-446 ✓  
2724-421 ✓  
2724-448 ✓  
2724-451 ✓

REVIEWER: Don Stuy

(ASSIGNED BY: \_\_\_\_\_)

EPA REG./FILE SYMBOL

ACTION CODE \_\_\_\_\_

SUBMISSION BARCODE \_\_\_\_\_

*Request for certificate  
of registration*

Date on Application

7-7-97

EPA Received Date

7-9-97

PM Received Date

7-11-97

Assigned in PRAT YES \_\_\_\_\_

NO \_\_\_\_\_

Completed by: S. Diana Hudson

Date \_\_\_\_\_

.....

## FINAL ACTION

Response Code \_\_\_\_\_

Response Date: / /

MOS: \_\_\_\_\_ (1) Cite-All

\_\_\_\_\_ (4) Not Applicable

\_\_\_\_\_ (8) Selective

CRP:

Yes \_\_\_\_\_ No \_\_\_\_\_

Restricted Use:

Yes \_\_\_\_\_ No \_\_\_\_\_

Manufacturing Use:

Yes \_\_\_\_\_ No \_\_\_\_\_

Exclusive Use:

Yes \_\_\_\_\_ No \_\_\_\_\_



RECEIVED

JUL 11 1997

OPP/BPPD

Wellmark

July 7, 1997

Mr. Willie Nelson Team 90  
Document Processing Desk (CERT)  
Office of Pesticide Programs - H7504C  
U.S. Environmental Protection Agency  
401 M Street SW  
Washington, D.C. 20460-0001

Dear Mr. Nelson:

Our overseas affiliates are requesting verification of U.S. registration for the following products:

	<u>EPA Reg. No.</u>
Altosid Liquid Larvicide	2724-392
Zoecon RF-437 Mosquito Growth Regulator SR-20	2724-446
Zoecon RF-292 Briquets	2724-421
Zoecon RF-330 Altosid Pellets Mosquito Growth Regulator	2724-448
Zoecon 9010 GR	2724-451

In order for us to complete the documentation, a certificate of registration letter bearing the EPA seal is needed from your office. We would greatly appreciate all of the above products being listed on one Gold Seal letter.

Because of continual requests for the same products, could you please provide us with six originals of this letter.

Please return the documents in the enclosed self addressed stamped envelope at your earliest convenience.

Thank you for your assistance in this matter and if you should have any questions, please contact me at 630/227-6016.

Sincerely,  
WELLMARK INTERNATIONAL

*Kathleen McLean*

Kathleen McLean  
Regulatory Project Assistant

Enclosure

**ACCEPTED**  
NOV 25 1990  
2724-448

# ZOECON RF-330 ALTOSID PELLETS

MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

## ACTIVE INGREDIENT:

(S)-Methoprene [isopropyl (2E,4E,7E)-  
11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoste]..... 4.00  
INERT INGREDIENTS:..... 96.00  
Total.....100.00

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

**NET WEIGHT : 25 lb (11.34 kg)**

## PRECAUTIONARY STATEMENTS

**ENVIRONMENTAL HAZARDS:** Do not apply to known fish habitat.

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including Culex and Culiseta spp., as well as adults of the floodwater mosquitoes such as Aedes, Anopheles and Psorophora spp. from treated sites.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID insect growth regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

HABITAT	RATES (lbs/acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
Bridge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste treatment settling ponds	5 - 10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE & DISPOSAL:** Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-448  
U.S. Patents 3,904,662 and 4,815  
0590-B-0132A

EPA Est. No.  
Made in USA  
© 1988 Zoecon



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
401 "M" St., S.W.  
Washington, D.C. 20460

EPA Reg.  
Number:

2724-448

Date of Issuance:

4/17/97

**NOTICE OF PESTICIDE:**

~~/~~ Registration  
~~X~~ Reregistration

Term of Issuance:

Unconditional

Name of Pesticide Product:

Zoecon RF-330 Altosid  
Pellets

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Sandoz Agro, Inc.  
1300 East Touhy  
Des Plaines, IL 60018

5520785/655  
17/15

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Reregistration Eligibility Document(s), EPA has reregistered the product listed above. Enclosed is a copy of your label stamped "**Accepted**". This action is taken under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Change the label by revising the EPA Registration Number to read, "EPA Reg. No. 2724-448".

3. Submit five copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Wnelson:308-8682:EPA#2724-448:methoprene:wp5.0/0414/97

Signature of Approving Official:

*James Z. Anderson*

Date:

4/17/97

**CONCURRENCES**

SYMBOL	EPA Form 8570-6						
SURNAME	<i>W. Nelson</i>						
DATE	04/14/97						



CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC)  
REQUEST FORM\*

#2

CR#: 97-0140

REQUESTOR NAME: Willie H. Nelson REQUEST DATE: 4/21/97  
TEL: (703) 308-8682 ORG.: BPDD ROOM: 5 MAIL CODE: 7501W  
(DIV./BR./SEC.)

CSF ATTACHED:

- ☒ YES If CSF is attached complete Item A and the chemical name in Item B.  
☐ NO If CSF is not attached complete Items A through C.

A. INFORMATION REQUIRED:

✓ Check Applicable Category

- ☒ Provide PCC and Tolerance Exemption Status For Food-Use Inert Ingredient(s)  
☒ Provide PCC for Non-Food Use Inert Ingredient(s)  
☐ Provide PCC for Active Ingredient(s)  
☐ Provide PCC for Dye  
☐ Determine if Fragrance is Acceptable for Use in Formulation  
☐ Other (Describe): \_\_\_\_\_

B. INGREDIENT INFORMATION:

Ingredient No. 1:

Chem. Name: \_\_\_\_\_

Trade Name: \_\_\_\_\_

CAS Reg. No.: \_\_\_\_\_

Ingredient No. 2:

Chem. Name: \_\_\_\_\_

Trade Name: \_\_\_\_\_

CAS Reg. No.: \_\_\_\_\_

Ingredient No. 3:

Chem. Name: \_\_\_\_\_

Trade Name: \_\_\_\_\_

CAS Reg. No.: \_\_\_\_\_

Ingredient No. 4:

Chem. Name: \_\_\_\_\_

Trade Name: \_\_\_\_\_

CAS Reg. No.: \_\_\_\_\_

C. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No./File Symbol: 2724-448 Product Name: \_\_\_\_\_  
Registrant: \_\_\_\_\_ Food-Use Pesticide: ☐ YES ☐ NO  
Percent in Formulation (For Fragrance/Dyes only): \_\_\_\_\_

INFORMATION REPORTED:

Ingredient No. 1:

PCC: \_\_\_\_\_

TOL STATUS: \_\_\_\_\_

OTHER INF.: \_\_\_\_\_

Ingredient No. 2:

PCC: \_\_\_\_\_

TOL STATUS: \_\_\_\_\_

OTHER INF.: \_\_\_\_\_

Ingredient No. 3:

PCC: \_\_\_\_\_

TOL STATUS: \_\_\_\_\_

OTHER INF.: \_\_\_\_\_

Ingredient No. 4:

PCC: \_\_\_\_\_

TOL STATUS: \_\_\_\_\_

OTHER INF.: \_\_\_\_\_

Completed By: LINDA

FON

Date Completed: 04/07/97

2 April 1997

\*Inert ingredient information may be entitled to confidential treatment\*





United States  
Environmental Protection Agency  
Washington, DC 20460

☐  
☐  
☒

Registration  
Amendment  
Other

OPP Identifier Number

256653

## Application for Pesticide - Section I

1. Company/Product Number Sandoz Agro, Inc./2724-448	2. EPA Product Manager P. Hutton	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sandoz Agro, Inc./RF-330 ALTOSID Pellets	PM# 90	
5. Name and Address of Applicant (Include ZIP Code) Sandoz Agro, Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of revised labels and updated CSF's to complete Phase 5 Reregistration requirements.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	<input type="checkbox"/> Glass	
			No. per container	<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 20-40 lbs.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Steven R. Spaulding	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (847) 390-3007
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature 	3. Title Manager, Regulatory Affairs	
4. Typed Name Steven R. Spaulding	5. Date 12 February 1997	



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "re-reg", reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



SANDOZ AGRO, Inc. - Label Review Sheet

FILENAME: L:\LABELS\CAHSPEC\  
02724448\paltpeLA.97A      COVERSHEET      January 1997  
UPDATE:  
PRODUCT: ZOECON RF-330      EPA REG. NO.:      2724-448  
ALTOSID PELLETS  
APPROVED      SUPERSEDES:  
:

OVERVIEW: Label submitted for reregistration, including nominal (ingredient statement), removal of fish habitat restriction statement, and other efforts to bring label uptodate and consistent with 30 and 150 briquets (375/421)

Page #	Description of Major Changes
1	Ingredient Statement revised to reflect nominal (changed label rate from 4.0% to 4.25%) Best if used by statement required (solid-degradation), changed from Not for sale or use after...
2	Revised Environmental Hazards per EPA approval to remove restriction on fish habitat statement but needed to be replaced by "This product is toxic...equipment washwaters." <i>Anopheles</i> species moved from floodwater complex to adult standing water mosquitoes listing Additional mosquito species added: <i>Coquillettidia</i> and <i>Mansonia</i> Table - dredge changed to <u>dredging</u> spoil sites and waste treatment settling ponds changed to waste treatment <u>and</u> settling ponds Additional use sites: Floodwater: cattail marshes Permanent: fish ponds, cattail marshes, water hyacinth beds, and vegetation-choked phosphate pits

[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence

[Prevents Nuisance Midge Emergence]

**ACTIVE INGREDIENT:**

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:\* ..... 4.25%

**INERT INGREDIENTS:** ..... 95.75%

**Total:** ..... 100.0%

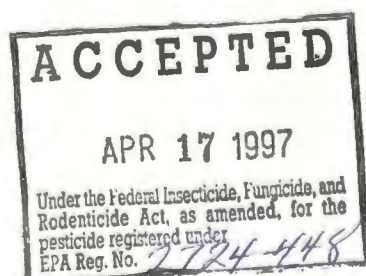
\*U.S. Patents: 3,904,662 and 3,912,815

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**Best if used by:**

**NET WEIGHT:**



## PRECAUTIONARY STATEMENTS

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rancid or equipment washwaters.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID® Pellets release ALTOSID® Insect Growth Regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Anopheles*, *Culex*, *Culiseta*, *Coquillettidia*, and *Mansonia* spp., as well as adults of the floodwater mosquitoes such as *Aedes* and *Psorophora* spp. from treated sites. ALTOSID Pellets also controls nuisance midge larvae.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID Insect Growth Regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes [or midges] which have reached the pupal or adult stage prior to treatment.



## APPLICATION SITES AND RATES:

<b>MOSQUITO HABITAT</b>	<b>RATES (Lb/Acre)</b>
<b><u>FLOODWATER SITES</u></b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, cattail marshes, woodland pools, floodplains, tires, other artificial water-holding containers	2.5-5
Dredging spoil sites, waste treatment and settling ponds, ditches and other manmade depressions	5-10
<b><u>PERMANENT WATER SITES</u></b>	
Ornamental ponds and fountains, fish ponds, cattail marshes, water hyacinth beds, flooded crypts, transformer vaults, abandoned swimming pools, construction and other manmade depressions, treeholes, other artificial water-holding containers	2.5-5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds, vegetation-choked phosphate pits	5-10
<b><u>MIDGE HABITAT</u></b>	<b>RATES (Lb/Acre)</b>
Midge larvae occur in natural and manmade aquatic habitats, both permanent and temporary. Examples of these include ditches, streams and ponds and natural and manmade lakes. Apply pellets uniformly to the water surface. Repeat application as necessary.	5-10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 to 10 lb/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are trademarks of Sandoz Ltd.

Sandoz Agro, Inc.  
1300 East Touhy Avenue  
Des Plaines, IL 60018

EPA Reg. No.: 2724-448

EPA Est. No.:  
Made in USA

[ ] indicates optional wording

**ZOECON RF-330 ALTOSID® PELLETS**  
**MOSQUITO GROWTH REGULATOR**

A Granular Product to Prevent Adult Mosquito Emergence

[Prevents Nuisance Midge Emergence]

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11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:\* ..... 4.25%

**INERT INGREDIENTS:** ..... 95.75%

**Total:** ..... 100.0%

\*U.S. Patents: 3,904,662 and 3,912,815

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**Best if used by:**

**NET WEIGHT:**

**ACCEPTED**

**APR 17 1997**

Under the federal Insecticide, Fungicide, and  
Rodenticide Act, as amended, for the  
pesticide registered under  
EPA Reg. No. 2724-448



## PRECAUTIONARY STATEMENTS

**ENVIRONMENTAL HAZARDS:** This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae. Using it in a manner other than that described by the label could result in harm to aquatic dipteran. Do not contaminate water when disposing of rancid or equipment washwaters.

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Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste settling ponds, vegetation-choked phosphate pits	5-10

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ALTOSID® Pellets and ALTOSID® Insect Growth Regulator are trademarks of Sandoz Ltd.

Sandoz Agro, Inc.  
1300 East Touhy Avenue  
Des Plaines, IL 60018

EPA Reg. No.: 2724-448

EPA Est. No.:  
Made in USA



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 31 1996

Mr. Steven Spaulding  
Sandoz Agro, Inc.  
1300 E. Touhy Avenue  
Des Plaines, Illinois 60018

Dear Mr. Spaulding:

Subject: Altosid Pellets

EPA Reg. No. 2724-448

Your submissions between 1993-1996 in support of the removal of the fish habitat labeling precaution statement

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A) requesting:

1. Removal of the statement "Do not use in fish-bearing waters", and

2. Modification of the labeling required statement "This product is toxic to aquatic invertebrates" to read, "This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae" **is acceptable provided that you:**

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Submit five (5) copies of the corrected final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

CONCURRENCES							
SYMBOL	7501W	7501W	7501W				
SURNAME	W. H. HARRIS	H. J. HARRIS	M. C. LINTON				
DATE	10/29/96	10/29/96	10/30/96				

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

-2-

The data submitted under your submission of April 2, 1991 were assigned the following EPA MRID Number(s)

EPA MRID NUMBER(s) :

TITLE OF REPORT(s)

440221-01

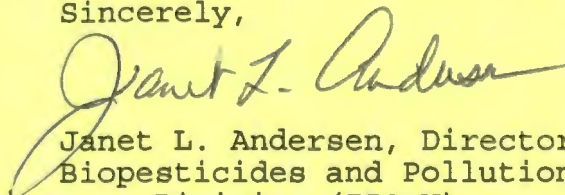
(S)-Methoprene Technical to Mysids (mysidopsis bahia) Under Flow-Through Conditions

440221-02

An Assessment of the Non-Target Effects of the Mosquito Larvicides, Bti and Methoprene, in Metropolitan Area Wetland

In future correspondence regarding these data, you should reference the assigned EPA MRID Numbers to facilitate our retrieval of these data. Please find a copy of the review attached to this letter for your records.

Sincerely,



Janet L. Andersen, Director  
Biopesticides and Pollution Prevention  
Division (7501W)

W Nelson / 10/29/30 308-8682-2722-337 Methoprene							
SYMBOL							
SURNAME							
DATE							



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 31 1996

Mr. Steven Spaulding  
Sandoz Agro, Inc.  
1300 E. Touhy Avenue  
Des Plaines, Illinois 60018

Dear Mr. Spaulding:

Subject: Altosid Pellets  
EPA Reg. No. 2724-448  
Your submissions between 1993-1996 in support of the  
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labeling.

If these conditions are not complied with, the registration  
will be subject to cancellation in accordance with FIFRA sec.  
6(e). Your release for shipment of the product constitutes  
acceptance of these conditions.

CONCURRENCES							
SYMBOL	750/W	7501W					
SURNAME	W. H. H. H.	McClintock					
DATE	10/28/96	10/30/96					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

-2-

The data submitted under your submission of April 2, 1991 were assigned the following EPA MRID Number(s)

EPA MRID NUMBER(s) :

TITLE OF REPORT(s)

440221-01

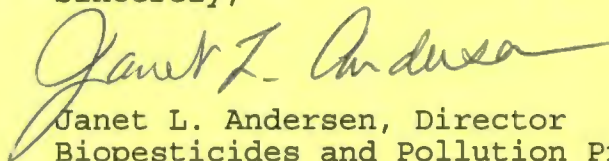
(S)-Methoprene Technical to Mysids (mysidopsis bahia) Under Flow-Through Conditions

440221-02

An Assessment of the Non-Target Effects of the Mosquito Larvicides, Bti and Methoprene, in Metropolitan Area Wetland

In future correspondence regarding these data, you should reference the assigned EPA MRID Numbers to facilitate our retrieval of these data. Please find a copy of the review attached to this letter for your records.

Sincerely,



Janet L. Andersen, Director  
Biopesticides and Pollution Prevention  
Division (7501W)

W Nelson / 10/29/30 308-8682-2111 CONCURRENCES Methoprene							
SYMBOL							
SURNAME							
DATE							



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 23 1999

OFFICE OF  
PREVENTION PESTICIDES AND  
TOXIC SUBSTANCES

**Memorandum**

Subject: Review of Ecotoxicity Data Submitted in Compliance with the Methoprene RED  
(DP Barcode D226999, Case No. 003099, MRIDs 440221-01 and 440221-02)

From: Mark J. Perry, Biologist  
Biopesticides and Pollution Prevention Division (7501W)

Thru: J. Thomas McClintock, Team Leader  
Biopesticides and Pollution Prevention Division (7501W)

To: Willie Nelson, Regulatory Action Leader  
Biopesticides and Pollution Prevention Division (7501W)

*Handwritten notes:*  
Mark J. Perry  
10/23/99  
JTH - 10/23/99

**Action Requested**

Sandoz Agro, Inc. submitted a chronic toxicity study performed with mysid shrimp (guideline reference 72-4) and a study evaluating non-target effects in metropolitan wetland areas (non-guideline). Both studies were performed with technical methoprene and were submitted in response to the methoprene RED. The non-guideline study was required by the Agency prior to reclassification of methoprene as a biochemical. This study also evaluated the use of *B. thuringiensis israelensis* as a mosquito larvicide.

**Results/Conclusion**

The non-target effects in metropolitan wetland areas (non-guideline) study is classified supplemental; it was not conducted following GLP regulations 40 CFR 160. Although the study may provide useful information, it does not satisfy the data requirement. In general, the results of the study indicate that, with field use of methoprene in wetlands, adverse ecological effects on non-target organisms were either not present or were unmeasurable due to natural variability or study design constraints.

The chronic toxicity (72-4) study was conducted according to acceptable procedures and determined the following values for methoprene technical to mysid shrimp (*Mysidopsis bahia*): LOEC of 25  $\mu\text{g a.i./L}$ , NOEC of 14  $\mu\text{g a.i./L}$ , and MATC > 14 and < 25  $\mu\text{g a.i./L}$  (geometric mean MATC = 19  $\mu\text{g a.i./L}$ ). This study was adequately conducted (core) and provides acceptable data. Although the results are valid, the expected effect on aquatic invertebrates cannot be evaluated without the estimated environmental concentration (EEC) determined from the recommended use levels for this product.



# DATA EVALUATION REPORT

METHOPRENE

STUDY TYPE: NON-GUIDELINE STUDY

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831

Primary Reviewer:

Sylvia S. Talmage, Ph.D., D.A.B.T.

Signature: Sylvia S. Talmage

Date: October 2, 1996

Secondary Reviewers:

Robert H. Ross, M.S., Group Leader

Signature: RHR

Date: 10-3-96

Paul G. Forsyth, Ph.D.

Signature: Paul G. Forsyth

Date: 10-3-96

Quality Assurance:

Susan Chang, M.S.

Signature: Susan Chang

Date: 10/3/96

## Disclaimer

This Data Evaluation Report may have been altered by the Biopesticides and Pollution Prevention Division subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464



**METHOPRENE**

Non-Guideline Study

EPA Reviewer: Mark J. Perry  
Biopesticides and Pollution Prevention Division  
EPA Team Leader: Roy D. Sjoblad, Ph.D.  
Biopesticides and Pollution Prevention Division

Date: 10-22-96

Date: 10/23/96

**DATA EVALUATION REPORT**

**MRID# & TITLE OF STUDY:** MRID 44022102, An Assessment of the Non-Target Effects of the Mosquito Larvicides, Bti and Methoprene, in Metropolitan Area Wetlands

**DB BARCODE:** D226999  
**REG./FILE#:** 002724-00375

**CASE:** 003099  
**CHEMICAL/BIOL#:** 105401 Methoprene

**COMPANY/SPONSOR:** Sandoz Agro, Inc.

**TEST MATERIAL:** Methoprene

**REVIEW CONCLUSION:** This non-guideline study is classified supplementary; it was not conducted following GLP regulations 40 CFR 160. The original data, particularly for the Wright County Long Term Experiment, should be provided in order to perform a more definitive evaluation. In general, the results of the studies indicated that, with field use of methoprene in wetlands, adverse ecological effects on non-target organisms were either not present or were unmeasurable due to natural variability or study design constraints.

**RECOMMENDATIONS:** The sponsor should provide copies of the original unpublished laboratory and field studies for review. The Wright County Long Term Experiment could serve as a Tier IV Simulated or Actual Field Testing for Aquatic Organisms (Guideline M 154A-34) if the entire report including raw data were submitted. A combination of the Wright County Long Term Experiment and the Wright County Historical Survey could serve as a Tier IV Simulated or Actual Field Testing for Birds (Subdivision M, Guideline 154A-33) if the entire report including raw data were submitted.

**ADEQUACY OF STUDY:** Supplementary; this study was not intended to fulfill a guideline requirement but was intended to support reregistration of methoprene.

**MATERIALS & METHODS:** The study summarizes five field studies in which the effects of the application of methoprene to Michigan wetlands on non-target organisms was evaluated. The individual studies were suggested and sponsored by the Scientific Peer Review Panel of the Metropolitan Mosquito Control District and addressed the long-term ecological effects of a larvicidal program. As such, these studies did not follow the principles of GLP as outlined in 40 CFR Part 160. Additional methodology is summarized under the discussion of the individual studies.

**REPORTED RESULTS:** The results were provided as summaries of the five individual studies.

1. In the Wright County Historical Survey, no statistical differences in growth, reproduction, or return rates of red-winged blackbird populations or species composition and density of invertebrates were found between wetlands treated with methoprene and untreated sites.



2. In the North Metropolitan Area Bird Survey, observed differences in bird populations between untreated wetlands and wetlands historically treated with either methoprene or another larvicide were not clearly treatment related. No distinction between methoprene-treated sites and sites treated with the other larvicide was made.
3. In the Lake Maria Study, no statistically significant changes in densities of zooplankton, insects, or benthic invertebrates were observed between the methoprene-treated and untreated areas of Lake Maria. However, densities were too low for the statistical evaluation to be rigorous.
4. In the Mallard Duckling Study, differences in duckling weight were observed after five days (first trial) between treated and untreated sides of three ponds but not after 30 days (second trial). Methoprene treatment did not change the abundance of aquatic insects compared to untreated parts of the ponds.
5. Results of the Wright County Long Term Experiment indicate that following three years of application of methoprene to Michigan wetlands, there were no significant effects on zooplankton or bird populations. Significant reductions in benthic invertebrates were limited to chironomids (midges) which are closely related to mosquitoes.

**DISCUSSION:** The synthetic insect growth regulator methoprene has been studied for over 20 years. Review of the published and unpublished literature and the summary of information submitted by the registration applicant indicate that the only ecological effect of concern, as indicated by laboratory toxicity studies, is reduced reproduction of some non-target invertebrates such as *Daphnia* sp. Results of multi-year field studies in which methoprene was applied to Michigan wetlands as well as two historical studies involving the comparison of previously treated and untreated wetlands in the state of Michigan showed that zooplankton and avian reproduction and density were not affected by methoprene treatment; in one study, densities of some aquatic insects (chironomids and other benthic flies) were reduced by methoprene treatment. However, natural variability, the length of time over which the studies were conducted, and the response at other sites make the results of the field studies difficult to interpret.

These studies were not conducted according to prescribed procedures and should be considered supplementary. Studies address the ecological consequences of a long-term larvicidal program. Although natural variability occurs among sites and confounding factors such as fluctuating water levels were present, the Wright County Long Term Experiment indicates that, with the exception of reduced numbers of midges, there were no observable adverse ecological effects within the three-year treatment period. More precisely, there were no statistically significant decreases in cladoceran (which had been identified as sensitive non-target organisms) density or species richness between treated and untreated sites over the three-year treatment period. It is the opinion of the Scientific Peer Review Panel and the reviewer that the Wright County Long Term Experiment study should be continued for several more years.

The published literature indicate that methoprene is not persistent in the environment; however, application of slow release formulations or briquets ensure its presence over time. Because analysis of natural waters for methoprene is difficult due to interfering substances, some effort to measure concentrations in containers held under natural environmental conditions should be made.

The published literature also indicate that methoprene is practically nontoxic to mammals and birds and is not a reproductive toxicant. In addition, metabolism in a variety of species has been demonstrated. Therefore, the lack of effects on avian populations at the studied sites is not unexpected.



Although the Wright County Long Term Experiment was well summarized and data were provided, the original reports are necessary to perform a definitive evaluation.

### DISCUSSION OF INDIVIDUAL STUDIES:

#### 1. Wright County Historical Survey

**Method:** The purpose of this study was to compare 10 wetlands in the state of Michigan that had been treated with methoprene for two or more consecutive years with 30 wetlands outside the boundary of treatment. Comparisons were made in terms of effects on growth and reproduction of nesting red-winged blackbirds, (during one year) the yearly return rate of male red-winged blackbirds (two-year study), and on zooplankton and benthic invertebrates (one-year study). Zooplankton were collected with funnel-traps and benthic aquatic invertebrates were sampled with benthic cores.

**Results:** No differences between treated and untreated sites were detected in average clutch size, egg size, nestling growth rates, fledgling mass or fledgling ages of red-winged blackbirds. "Reproductive success was highly variable among sites, but appeared to be lower at sites where marsh wrens and yellow-headed blackbirds were present." Return rates of males were lower in the two years of study, but could not be correlated with an effect on the food web as determined by territory size, harem size, and egg and nest survival probabilities. No statistical differences were found between the treated and untreated sites for red-winged blackbird populations ( $p=0.05$ ) or invertebrate populations ( $p=0.05$ ); the raw data were not provided.

**Discussion:** Natural variability inherently makes comparisons among sites difficult in field studies. As noted by the authors, drought during the study year had lowered water levels, eliminating some areas and reducing densities of invertebrates in others with the result that treatment was difficult to distinguish from natural variation. The authors also noted that the treated sites had not been treated for very many consecutive years and the number of treatments per year in preceding years was relatively low. This study can be considered preliminary rather than definitive.

#### 2. North Metropolitan Area Bird Survey

**Method:** Terrestrial breeding birds in treated and untreated wetlands in three counties were censused. Eleven sites historically treated with methoprene and 23 sites historically treated with *Bacillus thuringiensis israelensis* (Bti) were paired with untreated sites on the basis of their area, shape, vegetation, and water regimes. Sites were selected using a double-blind approach. Bird populations were surveyed twice (mid-May to early July) using the variable circular plot technique. Nests of tree swallows in wooden nest boxes were monitored in seven matched pairs of sites during three years to estimate occupancy rates, clutch size, egg success, nestling growth rates, and fledgling success. The authors did not distinguish between methoprene and Bti-treated sites. Raw data were not provided.

**Results:** Of 26 different species of birds, only densities of yellow-headed blackbirds was significantly lower on the treated wetlands and their densities were negatively correlated with number of years of previous treatment. Growth of tree swallow nestlings was slightly retarded in treated wetlands during the first study year with nestlings from treated wetlands fledging about 2 days later,



but at approximately the same mass as those in non-treated wetlands; differences in fledgling age were not detected in the second and third years of the study.

**Discussion:** The study is not useful for ascertaining the effects of methoprene on bird populations as the investigators did not distinguish between methoprene and Bti-treated sites. In addition, as noted by the authors, many of the species censused are only weakly dependent on wetlands, effects on tree swallow fledgling growth were variable from year to year, and the small number of sites limited the power of the study to detect small effects of treatment. The study is not useful for ascertaining the effects of methoprene on bird populations.

### 3. Lake Maria Study

**Method:** Two wetland areas were trisected radially with curtains of polyolefin material. In April, one sector of a wetland was treated with a 150-day methoprene briquet (water concentration not stated/measured) and the other two sectors were treated with placebos. All sectors of the other wetland area received placebos. The different areas were sampled (time not stated) for zooplankton with funnel traps and for benthic invertebrates with benthic cores. A pre-treatment census was not mentioned.

**Results:** No statistically significant changes in densities of zooplankton, insects, or benthic invertebrates were observed between the treated and untreated sites.

**Discussion:** Few details of the study were provided. Aquatic organisms were not identified, but it can be assumed that they were similar to those in the accompanying studies. It appears that only one area was treated, although untreated areas were part of the same wetland. If present, larvicidal action should have been observable; however, it was noted by the authors that densities of the organisms of concern, benthic invertebrates, were too low to provide a rigorous test of the action of the larvicide. It was also stated that the dosage of methoprene was high enough to cause effects, but dosage was not stated. The study can be considered supplementary.

### 4. Mallard Duckling Study

**Methods:** Three ponds were bisected with double plastic barriers; randomly selected halves were treated with either methoprene briquets or placebos. Broods of 10 human-imprinted ducklings were placed in each wetland half and growth was observed for 5 (first trial) or 31 days (second trial) after initiation of treatment. Briquets stranded by receding water levels were replaced. Benthic organisms (food for the foraging ducklings) were sampled prior to and post-treatment. Floating traps were used to sample emerging insects.

**Results:** In the first trial ducklings from the treated site weighted less after 5 days of foraging than ducklings from the untreated site (no data provided); in the second trial, there was no difference in weights of ducklings between the treated and untreated halves. No significant differences in the density of benthic larvae or emerging adults were found between the sites. Data were not provided.

**Discussion:** No conclusions can be drawn from this study as weight differences of ducklings observed in the first trial were not evident in the second, longer trial. Treatment in the first trial was too short to affect insect densities and treatment during the second trial did not change the abundance of insects. Methoprene concentrations were not measured.



### 5. Wright County Long Term Experiment (WCLTE)

**Method:** This is a 5-year study (2-years pre-treatment and 3 years of treatment) of 17 wetland sites (9 reference sites and 8 methoprene treatment sites) in Wright County, Michigan. Six applications/year during spring and summer at rates ranging from 1.1 to 13.2 lbs/acre were made; the material was in the form of a 20-day release granule formulation. Treatments were monitored with bucket samplers placed in each wetland to measure the amount of material that was applied. Monitoring also included emergence success of mosquito larvae collected from treated and untreated sites. In addition to sampling for mosquitoes, populations of zooplankton and benthic invertebrates were sampled at 3-4 week intervals during the spring and summer of each year. Results from treatment sites were compared with reference sites using an ANOVA in three ways: date by date within each year, on a yearly basis across dates within each year, and averaged over the three treatment years ( $\alpha = 0.05$ ). Breeding birds were censused and blackbirds were examined for reproduction and behavior. Data were provided in graphs and tables.

**Results:** The presence of methoprene at the sites was indicated by the reduction in emergence of mosquito larvae during the last two years of the study. In 1992 emergences of collected larvae were 72% at the reference sites and 17% at the treated sites; the respective values in 1993 were 70% and 10%.

No effects on zooplankton occurred over the three years as indicated by species diversity, density, size, or reproduction. Although no effects on benthic invertebrates were detected during the first year of treatment, density and biomass were reduced compared with the control sites during the second and third year. Decreases at the treated sites were primarily due to reduced populations of chironomid larvae (midges) and other primitive flies. Midges were the most abundant and diverse group of benthic invertebrates at the sites.

Censuses of 19 breeding bird populations and a detailed study of red-winged blackbirds showed no consistent changes during the years of study. The censuses included three species that feed primarily on aquatic insects (soras, Virginia rails, and marsh wrens).

**Discussion:** Reduced densities of aquatic insects, particularly midges, which are closely related to mosquitoes, would be expected. Although the larvicidal program is aimed at mosquito control, the control of midges might not be considered detrimental to the environment unless some species of wetland birds are dependent on midges as their major food source. There were no declines in cladocerans which had been identified as sensitive non-target organism.

The red-winged blackbird is not dependent on wetlands for habitat and food but was the most abundant species and adequate for sampling. If possible, reproduction and development of the most abundant species of wetland species that feeds primarily on aquatic insects should be studied.

# DATA EVALUATION REPORT

(S)-METHOPRENE TECHNICAL

STUDY TYPE: LIFE-CYCLE - MYSID SHRIMP (72-4)

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831

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Paul G. Forsyth, Ph.D.

Signature: *Paul G. Forsyth*

Date: 10-3-96

Secondary Reviewers:

Robert H. Ross, M.S., Group Leader

Signature: *RH Ross*

Date: 10-3-96

Sylvia S. Talmage, Ph.D., D.A.B.T.

Signature: *Sylvia S. Talmage*

Date: October 5, 1996

Quality Assurance:

Susan Chang, M.S.

Signature: *SSS Chang*

Date: 10/3/96

## Disclaimer

This Data Evaluation Report may have been altered by the Biopesticides and Pollution Prevention Division subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464



(S)-METHOPRENE TECHNICAL

Mysid Life-Cycle Study (72-4)

EPA Reviewer: Mark J. Perry  
Biopesticides and Pollution Prevention Division  
EPA Team Leader: Roy D. Sjoblad, Ph.D.  
Biopesticides and Pollution Prevention Division

Date: 10-22-96  
Date: \_\_\_\_\_

**DATA EVALUATION REPORT**

**MRID# & TITLE OF STUDY:** MRID 44022101, (S)-Methoprene Technical - Chronic Toxicity to Mysids (*Mysidopsis bahia*) Under Flow-Through Conditions

**DP BARCODE:** D226999

**CASE:** 003099

**REG./FILE#:** 002724-00375

**CHEMICAL/BIOL#:** 105401 Methoprene

**COMPANY/SPONSOR:** Sandoz Agro, Inc., 1300 E. Touhy Avenue, Des Plaines, Illinois 60018

**TEST MATERIAL:** (S)-Methoprene Technical

**REVIEW CONCLUSION:** This study was conducted according to acceptable procedures and determined the following values for (S)-methoprene technical to mysid shrimp: LOEC of 25  $\mu\text{g a.i./L}$ , NOEC of 14  $\mu\text{g a.i./L}$ , and MATC > 14 and < 25  $\mu\text{g a.i./L}$  (geometric mean MATC = 19  $\mu\text{g a.i./L}$ ). This study was adequately conducted and provided useful data.

**RECOMMENDATIONS:** None

**ADEQUACY OF STUDY:** Core

**MATERIALS & METHODS:** The study procedures followed those of the Springborn Laboratories, Inc. (Wareham, MA) protocol entitled "(S)-Methoprene - Life-Cycle Toxicity Test with Mysids (*Mysidopsis bahia*), Following FIFRA Guideline 72-4" (Springborn Laboratories Protocol #:081295/FIFRA/530/s-methoprene [1995] and Protocol Amendment #1 [1995]). The study was conducted in accordance with GLP 40 CFR 160 with the exception of routine water screening and food analyses for pesticides, PCB's, and toxic metals. The water screening and food analyses were conducted using standard U.S. EPA procedures by Lancaster Laboratories (Lancaster, PA). No protocol deviations were noted and the study was acceptably conducted. The test material, (S)-Methoprene technical (Lot No. 5S1008, CAS# 40596-69-8), was received from Sandoz Agro, Inc. (Dallas, TX) and was stored frozen. The test material was an amber liquid with a purity of 95.311%, molecular weight of 310.5 g/mol, water solubility of 0.52 ppm, and vapor pressure of < 1 mm Hg. An analytical standard of (S)-Methoprene (Lot No. 95-24), was received from the same source and was an amber liquid with a purity of 95.21  $\pm$  0.01%. The analytical standard was also stored frozen.

The mysids ( $\leq 24$  hours old) used in these tests were obtained from laboratory cultures maintained at Springborn Laboratories (SLI Lot #95A107) and were kept in recirculated, filtered artificial seawater for 14 days prior to the test. Juvenile mysids ( $\leq 24$  hours old) were collected and fed brine shrimp (*Artemia salina*) nauplii, *ad libitum*, twice daily, with one feeding supplemented with Selco®, a liquid food supplement. Food sources were analyzed routinely and found to be acceptably free of pesticides, PCB's, and metals considered toxic to mysids.



Artificial seawater used as dilution water during these tests was prepared by the addition of a commercially prepared salt formula (hw-MARINEMIX®) to filtered soft freshwater having a hardness of 20 to 40 mg/L as  $\text{CaCO}_3$ , with a final salinity of  $25 \pm 3\text{‰}$ . The prepared dilution was aerated vigorously for approximately 24 hours, then allowed to aerate for an additional 24 hours prior to use. Routine analyses found no toxic concentrations of pesticides, PCBs, or toxic metals in the dilution water source. Mysids maintained in artificial seawater prepared from the same source as the artificial seawater used in this study have successfully survived and reproduced over several generations.

Nominal concentrations selected for the test material were 9.4, 19, 37, 75, and 150  $\mu\text{g a.i./L}$ . A 30 mg a.i./mL stock solution was prepared by dissolving 1.584 g of test material with acetone to volume in a 50 mL volumetric flask. Additionally, a 0.50 mL/mL solvent stock solution was prepared by diluting 50 mL of acetone with distilled water to volume in a 100 mL volumetric flask.

The life-cycle test was conducted using an exposure system consisting of a constant-flow serial diluter, a temperature-controlled water bath, and a set of 14 exposure aquaria (two per test concentration level). Each aquarium contained two mysid retention chambers made of glass Petri dishes covered with screen which were used to maintain non-paired mysids during the study. Pairing chambers, used to house sexually mature male and female organisms, were cylindrical glass jars having two screen-covered holes. The aquaria systems allowed for adequate solution exchange via siphon drains. The 150  $\mu\text{g a.i./L}$  nominal treatment was attained by delivering 0.0015 mL/min of the test material stock solution to a mixing chamber which also received 0.302 L/min of dilution water. The stock solution was proportionally diluted (50% dilution factor) to provide the remaining nominal test concentrations. A similar system was used to deliver the acetone stock solution to the diluter system of the solvent test chambers, providing an acetone concentration equivalent to the acetone concentration in the highest test solution. The solution exchange system operated at a rate of approximately 15 aquarium volume additions per day to provide a 90% test solution replacement rate of approximately 3.5 hours. The entire operating system was illuminated with fluorescent lighting for 16 hours daily followed by 8 hours darkness.

"Mysids,  $\leq 24$  hours old, were collected from the Springborn culture unit and divided among 28 beakers. The beakers contained culture water and were held in a waterbath maintained at  $25 \pm 2^\circ\text{C}$ . The organisms were impartially selected and distributed to the beakers by adding five organisms at a time to each beaker until each beaker contained 15 mysids. Each group of 15 mysids was then transferred to one of the 28 labeled retention chambers (two per aquarium). The test was initiated when the retention chambers were placed in their respective test aquaria. Each test aquarium contained two retention chambers, yielding 30 mysids per replicate vessel and 60 organisms for each treatment level and control."

Upon reaching sexual maturity (Day 15), mature male/female pairs within each exposure aquarium were transferred from the retention chambers to the 10 glass pairing jars (one pair per jar). The remaining mysids were all placed in one of the initial retention chambers within each aquarium and maintained for the duration of the chronic test. Male mysids from this pool were used to replace dead males removed from the paired groups. Females that died in pairing jars were not replaced. If development of brood pouches, distinguishing females from males, was delayed due to toxicant exposure, all test organisms were maintained in the retention chambers until maturity was observed or until test termination. Mysids were fed live brine shrimp (*Artemia salina*) nauplii twice daily. Before pairing, at least one of the daily feedings was enriched with Selco®. After pairing, the mysids were fed Selco®-enriched brine shrimp nauplii once every other day.



During the first 14 days, observations were made for mortality and any abnormal appearance or behavior. After pairing (Day 15), mortality of the paired mysids, the number of offspring produced by each female, and any abnormal appearance or behavior was recorded. Observations were made daily throughout the study. Dead mysids were removed and discarded.

At test termination, all mysids were sacrificed and measured for individual body length (nearest 0.1 mm) and total dry body weight (nearest 0.01 mg). Reproductive success was calculated for each replicate aquarium as the ratio of the total number of offspring produced to the total number of females contained within each chamber per reproductive day. The number of female reproductive days was determined as the number of days that an individual was alive, counting the day that offspring were first observed in any control (i.e., Day 18 represents reproductive day 1).

Daily measurements were made for water temperature, dissolved oxygen concentration, pH, and salinity in each replicate of each treatment. Samples were removed from each replicate test solution and control on days 0, 7, 14, 21, and 28 and analyzed for test material concentration.

Data from the paired and unpaired mysids were statistically analyzed for treatment effects. Endpoints analyzed for first generation ( $F_0$ ) mysids included survival, growth (i.e., body weights and lengths), and reproduction. Reproductive success was determined only for the paired organisms. Bartlett's Test was used to test for homogeneity of variance (99% certainty level). Student's t-test was conducted for each endpoint to compare solvent and negative controls, resulting in no significant difference. Therefore, solvent and negative control endpoints were pooled for the remaining comparisons between controls and treatments. The Williams' Test was used to determine treatment level effects (95% certainty level). The Maximum-Acceptable-Toxicant-Concentration (MATC), or the theoretical threshold concentration of the test material expected to produce no deleterious effects to mysids, was estimated at the 95% certainty level. Also determined were the Lowest-Observed-Effect Concentration (LOEC) and the No-Observed-Effect Concentration (NOEC).

**REPORTED RESULTS:** Water quality parameters measured during the 28-day exposure remained within acceptable limits. Analyses of test material concentrations in the aquaria exhibited consistency between replicates and sampling intervals and the expected concentration gradient across treatment levels was maintained throughout the 28-day test. However, mean measured concentrations ranged from 66 to 77% of the nominal concentrations and defined the concentrations tested as 7.2, 14, 25, 50, and 98  $\mu\text{g a.i./L}$ . Coefficients of variation averaged 15% for all mean measured concentrations.

Survivals of the  $F_0$  mysids were 90 and 92% for the control and solvent control, respectively, with no statistical difference between the two (pooled control survival = 91%). Survivals of 78, 78, 82, 83, and 57% were observed for mysids exposed to mean measured test material levels of 7.2, 14, 25, 50, and 98  $\mu\text{g a.i./L}$ , respectively. Only the 98  $\mu\text{g a.i./L}$  concentration was determined to be statistically different from the pooled control results. For this reason, results for that treatment were eliminated from further chronic statistical analyses.

No statistical difference was observed between control and solvent control mysids for reproductive success (0.6 and 0.39 offspring/female/reproductive day, respectively) and these groups were pooled (mean = 0.50 offspring/female/reproductive day). Mysid reproduction in the treatment levels that did not adversely affect survival, i.e., 7.2, 14, 25, and 50  $\mu\text{g a.i./L}$ , ranged from 0.22 to 0.45 offspring/female/reproductive day and were determined not to be significantly different from the pooled control organisms with respect to reproductive success.



The mean body lengths of male and female control mysids were 7.0 and 6.9 mm, respectively, while the solvent control mysids measured 7.2 and 7.0 mm for males and females, respectively. The control and solvent control body length measurements were not statistically different, and the pooled lengths for control males and females were 7.1 and 7.0, respectively. For exposure concentrations to the test material of 7.2, 14, 25, and 50  $\mu\text{g a.i./L}$ , the respective body lengths for male mysids were 7.1, 7.2, 7.2 and 7.1 mm, while the respective body lengths for females were 7.2, 7.1, 7.2, and 6.9 mm. Both male and female body lengths were not statistically different from the pooled control body lengths. These data indicate that the test material "at levels  $\leq 5.0 \mu\text{g a.i./L}$ " did not adversely affect organism growth based on body length. Obviously, this should read "at levels  $\leq 50 \mu\text{g a.i./L}$ ".

The mean body weights for the control and solvent control male mysids were 0.88 and 0.82 mg, respectively, while those for females were 1.0 and 0.90 mg, respectively. There were no statistical differences between control and solvent control groups for either males or females, allowing for pooled averages of 0.85 and 0.95 mg for males and females, respectively. For exposure concentrations to the test material of 7.2, 14, 25, and 50  $\mu\text{g a.i./L}$ , the respective dry body weights for male mysids were 0.78, 0.82, 0.75, and 0.78 mg, while respective dry body weights for females were 0.93, 0.93, 0.93, and 0.81 mg. Statistically significant reduced dry body weights occurred in exposure concentrations to the test material of 25 and 50  $\mu\text{g a.i./L}$  for males and 50  $\mu\text{g a.i./L}$  for females.

"Based on the results of this study, the LOEC and NOEC of (S)-Methoprene technical for mysid survival, reproductive success and growth (total body length and dry weight) was determined. Dry body weight of male mysids was determined to be the most sensitive indicator of toxicity of (S)-Methoprene technical to mysids. The LOEC and NOEC, based on male dry body weight, was 25 and 14  $\mu\text{g a.i./L}$ , respectively. The Maximum-Acceptable-Toxicant Concentration (MATC) was calculated to be  $> 14$  and  $< 25 \mu\text{g a.i./L}$  (Geometric Mean, MATC = 19  $\mu\text{g a.i./L}$ ). These data provided a MATC which corroborated the conservatively estimated MATC (i.e., 24  $\mu\text{g a.i./L}$ ) determined during previously conducted life-cycle tests (SLI Report #92-11-4518)."

**DISCUSSION:** This study was conducted following acceptable procedures outlined in FIFRA Guideline 72-4, Subdivision E of the U.S. EPA Pesticide Assessment Guidelines (1982). This study determined the following values for (S)-methoprene technical to mysid shrimp: LOEC of 25  $\mu\text{g a.i./L}$ , NOEC of 14  $\mu\text{g a.i./L}$ , and MATC  $> 14$  and  $< 25 \mu\text{g a.i./L}$  (geometric mean MATC = 19  $\mu\text{g a.i./L}$ ). These values are based on the dry body weight for male mysids, which was determined to be the most sensitive performance criterion measured in these tests. The mortality data (presented as "Percent Survival") were reported to be significant only at the 98  $\mu\text{g a.i./L}$  level, and sublethal data at this level were not used in statistical calculations.

Although mortality was measured, no  $\text{LC}_{50}$  was calculated since 50% mortality was never achieved, nor did the data seem to follow a dose-response curve, i.e., percent survival was lower at the two lower treatment concentrations (78% for both) than at the next two higher treatment concentrations (82 and 83%) but lowest at the highest concentration of 98  $\mu\text{g a.i./L}$  (57%). The survival data shown in Table 1 are the actual percentages measured in each aquarium, with the mean given for the two aquaria per concentration. The reduction in survival does not follow a dose-response fashion, except that the greatest mortality occurs in the highest treatment concentration level. Although the Williams' Test showed no significant difference in survival between each of the treatments and the pooled controls (at  $\leq 50 \mu\text{g a.i./L}$ ), the use of only two data points (per treatment) does not give a standard deviation and is of questionable statistical validity.

The authors report no significant effect of the test material on reproductive success in mysids. However, the reproductive data shown in Table 1 is presented in a similar fashion to the survival data. When the number of reproducing females and the number of reproductive days are divided out, all of the reproductive data within an aquarium is reduced to a single number. Again, the use of only two values is of questionable statistical validity. The reviewer repeated the statistical analyses of the author regarding survival and reproduction and concurs with the author's conclusion.



TABLE 1. Summary of the first generation ( $F_0$ ) survival and reproductive success (offspring/female/reproductive day) during the 28-day life-cycle exposure of mysids (*Mysidopsis bahia*) to (S)-Methoprene Technical

Mean Measured Concentration $\mu\text{g a.i./L}$	Replicate	Percent Survival <sup>a</sup>	Reproductive Success <sup>a</sup>
Control	A	90	0.41
	B	90	0.79
	Mean	90	0.60
Solvent Control	A	90	0.33
	B	93	0.44
	Mean	92	0.39
Pooled Control <sup>b</sup>	Mean	91	0.50
7.2	A	73	0.42
	B	83	0.29
	Mean	78	0.36
14	A	73	0.44
	B	83	0.46
	Mean	78	0.45
25	A	87	0.49
	B	77	0.25
	Mean	82	0.37
50	A	83	0.18
	B	83	0.25
	Mean	83	0.22
98	A	60	0.083
	B	53	0.0094
	Mean	57 <sup>c</sup>	0.046 <sup>d</sup>

Data taken from Table 3, p. 34, MRID 44022101.

<sup>a</sup> Values presented have been rounded to two significant figures.

<sup>b</sup> Since control and solvent control data were not determined to be significantly different, all treatment data were compared to the pooled control data.

<sup>c</sup> Significantly different ( $p \leq 0.05$ ) from the pooled control (Williams' Test).

<sup>d</sup> Since organism survival was adversely affected, this treatment level was excluded from statistical analysis to determine treatment effects for body length, body weight, and reproductive success.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUL 26 1996

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Mr. Steven R. Spaulding  
Sandoz Agro, Inc.  
1300 East Touhy Avenue  
Des Plaines, Illinois 60018-3300

Dear Mr. Spaulding:

Subject: Methoprene Product Supported for Reregistration  
(See attached list of products covered by this letter)

Thank you for your letter and transmittal dated April 22, 1996, submitted in response to the Agency's [Willie H. Nelson's request of March 20, 1996] requesting verification of all **methoprene products supported by registration**. As a follow-up to this request, the items listed below are items which must be completed before reregistration of these products can be completed.

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the files for methoprene products in an attempt to complete the reregistration process for these products, and to assist in this attempt the following information is required:

a. Application for reregistration (use EPA Form 8570-1). Complete and sign this form. In Section II of this form, check the box "Other" and insert the phrase "Application for Reregistration" in the Explanation box.

b. Submit five (5) copies of revised draft label and labeling. Include on the label all changes specified by the RED for methoprene products, e.g.: LABELING REQUIREMENTS FOR END-USE PRODUCTS and LABELING REQUIREMENTS FOR MANUFACTURING USE PRODUCTS (see attached methoprene information sheet).

c. All applicable methoprene products must comply with requirements for Worker Protection Standard" according to PR Notice 95-3 (see attached).

d. Submit two (2) copies of the current Confidential Statement of Formula (CSF) (EPA Form 8570-4, revised February 85). Two completed and signed CSF forms must be submitted for the basic formulation and for each alternate formulation for each affected product. If CSFs are not provided for the alternate formulas, they will not be registered and will no longer be acceptable. Instructions for completing the CSF form is found in the Appendix of the Pesticide Reregistration Handbook sent out with the RED.

Until the Estuarine Invertebrate Life Cycle Study review is completed and found acceptable, and it is determined that methoprene poses no problem when used in aquatic applications, labeling restrictions will have to remain on the labeling:

"This product is toxic to aquatic invertebrates. Using it in a manner other than that described by the label could result in harm to aquatic invertebrates. Do not contaminate water when disposing of rinsate or equipment washwaters"

Should you have any questions concerning this letter, please free to contact Mr. Willie H. Nelson at (703) 308-8682.

Sincerely,

*Janet L. Andersen*

Janet L. Andersen, Acting Director  
Biopesticides and Pollution Prevention  
Division (7501W)



PRODUCT MASTER LIST - METHOPRENE

1. Zoecon RF-275 Pressurized Spray  
EPA Reg. No. 2724-338
2. Zoecon RF-291 Emulsifiable Conc.  
EPA REG. No. 2724-352
3. Zoecon RF - 293 Methoprene Bolus for Beef & Dairy Cattle  
EPA Reg. No. 2724-356
4. Zoecon RF - 297 Aerosol  
EPA Reg. No. 2724-360
5. ALTOSID CP-10 (cattle premix 10%)  
EPA Reg. No. 2724-367
6. Zoecon Granular IGR Cattle Supplement  
EPA Reg. No. 2724-372
7. Zoecon Block IGR Cattle Supplement  
EPA Reg. No. 2724-373
8. Altosid Briquets  
EPA Reg. No. 2724-375
9. Kabat Tobacco Protector Conc.  
EPA Reg. No. 2724-377
10. Kabat Tobacco Protector Conc.  
EPA Reg. No. 2724-384
11. Altosid Liquid Larvicide  
EPA Reg. No. 2724-392
12. Altosid Liquid Larvicide Conc.  
EPA Reg. No. 2724-393
13. Zoecon RF-299 RTU Carpet Pump Spray  
EPA Reg. No. 2724-401
14. Zoecon RF-322 Ovicidal Pump Spray  
EPA Reg. No. 2724-404
15. Zoecon RF-329 Ant Growth Regular  
EPA Reg. No. 2724-420
16. Zoecon RF-292 Briquet  
EPA Reg. No. 2724-421



17. Zoecon RF-372 Collar  
EPA Reg. No. 2724-426
18. Zoecon RF-342 Emulsifiable Conc.  
EPA Reg. No. 2724-427
19. Methoprene Technical  
EPA Reg. No. 2724-441
20. S-Mehtoprene Technical  
EPA Reg. No. 2724-442
21. Zoecon RF-379 Mosquito Growth  
Regulator SR-20  
EPA Reg. No. 2724-446
22. Zoecon RF-330 Altosid Pellets  
EPA Reg. No. 2724-448
23. Altosid Granules  
EPA Reg. No. 2724-ULR
24. Zoecon Apex 5E  
EPA Reg. No. 2724-452
25. Zoecon 9026 Fogger  
EPA Reg. No. 2724-454
26. Zoecon 9202 Aerosol  
EPA Reg. No. 2724-455
27. Zoecon 9007 Concentrate  
EPA Reg. No. 2724-459
28. Zoecon 9207 Collar  
EPA Reg. No. 2724-460
29. Zoecon 9307 Pump Spray  
EPA Reg. No. 2724-462
30. Sandoz 9309 Fogger  
EPA Reg. No. 2724-464
31. Sandoz 9311 Aerosol  
EPA Reg. No. 2724-465
32. Sandoz 9412 Mousse Lite  
EPA Reg. No. 2724-467

33. Sandoz 9116 Mousse  
EPA Reg. No. 2724-468
34. Sandoz 9503 Aerosol  
EPA Reg. No. 2724-UTN
35. Methoprene/ Chlorpyrifos  
Combination Collar for Dogs  
EPA Reg. No. 2724-UTR
36. Altosid 5E - FZ - 515 (Diacon)  
EPA Reg. No. 55947-94
37. Zoecon Insect & Mite Houseplant Mist  
EPA Reg. No. 55947-127
38. Zoecon Insect & Mite Houseplant Mist  
EPA Reg. No. 55947-128
39. Zoecon Insect & Mite Houseplant Mist Conc.  
EPA Reg. No. 55947-129
40. Sandoz 9404 Spray (Roussel)  
EPA Reg. No. 55947-158

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 22 1995

Mr. Steven R. Spaulding  
Senior Registration Specialist  
Sandoz Agro, Inc.  
1300 East Touhy Avenue  
Des Plaines, Illinois 60018-3300

Dear Mr. Spaulding:

Subject: Methoprene Reregistration  
EPA Reg. No.: 2724-448  
(Case # 0030; Chemical # 105401)  
Kabat Tobacco Protector (5%)  
Acute Toxicity Studies  
Submitted August 8, 1994

Thank you for your transmittal of August 8, 1994, submitted in response to reregistration requirements as per 40 CFR sec (s) 152.60, 152.65 and 152.70 of Subpart-D-Reregistration Procedures. Sandoz submitted the required acute toxicity studies to support methoprene reregistration requirements related to the end-use product: KABAT TOBACCO PROTECTOR (80%).

The data submitted under your of August 8, 1994, were assigned the following EPA MRID Number (s):

<u>EPA MRID Number (s)</u>	<u>Title of Studies</u>
433338-01	Acute Oral Toxicity Study
433338-02	Acute Dermal Irritation Study
433338-03	An Acute (4-Hour) Inhalation Toxicity Study
433338-04	Primary Eye irritation Study
433338-05	Primary Dermal Irritation Study
433338-06	Closed Patch Repeated Insult Dermal Sensitization Study.

In future correspondence regarding these data, you should reference the assigned EPA MRID number to facilitate our retrieval of these data. All of these data were found acceptable.

## CONCURRENCES

SYMBOL	W14 NC 1000/303-8682/2724-448/methoprene
SURNAME	
DATE	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

-2-

LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING METHOPRENE

- A. the labels and labeling of all products must comply with EPA's regulations and requirements. Follow the instructions in the product Reregistration Handbook with respect to labels and labeling, as well as current labeling requirements.
- B. Based on the reviews of the generic data the following additional label statement is required:  
  

**"This product is toxic to aquatic invertebrates. Using it in a manner other than that described by the label could result in harm to aquatic invertebrates. Do not contaminate water when disposing of rancid or equipment washwaters"**
- C. The above statement is needed, because there was one outstanding data gap identified by the Methoprene Standard: **An Estuarine invertebrate Life Cycle Study.** Although this study is needed to assess the long term exposure to estuarine invertebrates, the Agency has determined (via DCI) that reregistration of Methoprene can precede at this time, because most of the use for Methoprene do not involve significant exposure to estuarine invertebrates. Labeling restrictions as proposed will be taken care of this issue until the Estuarine Invertebrate Life Cycle study can be submitted, reviewed and found acceptable.
- D. Pursuant to Pesticide Regulation (PR) Notice 95-3, Methoprene appears on the list of 114 active ingredients currently subject to the WPS requirements that meet the lower toxicity criteria; as such, the Environmental Protection Agency (EPA)/Biospecticides and Pollution Prevention Division (BPPD) will permit registrants of Methoprene to reduce the Worker Protection Standard interim restricted entry intervals (REIs) from 12 to 4 hours for this low risk pesticide. **Where applicable, Sandoz must submit upgraded labels complying with the requirements as stipulated in PR Notice 95-3, concerning WPS REIs.**

Please find a copy of the review attached for your records.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

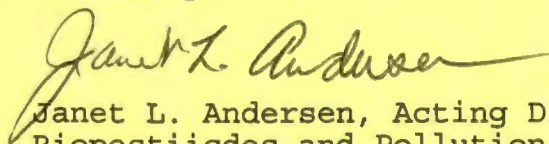
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

-3-

In order for BPPD to precede with the REREGISTRATION of this product we must receive five copies of your final printed label.

If you have any questions concerning this letter, please feel free to contact Mr. Willie H. Nelson at (703) 308-8682.

Sincerely,



Janet L. Andersen, Acting Director  
Biopesticides and Pollution Prevention  
Division (7501W)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

433338-①①

**CORPORATE HEADQUARTERS**

TEL. 708.699.1616

Document Processing Desk  
Room 266A, Crystal Mall 2  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202

Attn: Richard King, Chemical Review Manager  
Special Review and Reregistration Division (7508C)

August 8, 1994

**Subject: METHOPRENE REREGISTRATION**  
**(Case #0030; Chemical #105401)**  
**ALTOSID PELLETS - ACUTE TOXICOLOGY STUDIES**

Dear Mr. King:

Please find enclosed 3 copies of the following studies which are being submitted to support methoprene reregistration requirements related to the end-use product ALTOSID Pellets:

1. Blaszcak, D.L. (1994). Acute Oral Toxicity Study of Altosid Pellets In Rats, (EPA Reg. No. 2924-448). Pharmacology:LSR Study Number 93-0856.
2. Blaszcak, D.L. (1994). Acute Dermal Toxicity Study of Altosid Pellets in Rabbits, (EPA Reg. No. 2724-448). Pharmacology:LSR Study Number 93-0857.
3. Blaszcak, D.L. (1994). Primary Eye Irritation Study of Altosid Pellets in Rabbits, (EPA Reg. No. 2724-448). Pharmacology:LSR Study Number 93-0859.
4. Blaszcak, D.L. (1994). Primary Dermal Irritation Study of Altosid Pellets in Rabbits, (EPA Reg. No. 2724-448). Pharmacology:LSR Study Number 93-0858.

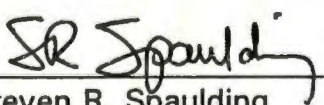


5. Blaszcak, D.L. (1994). Closed Patch Repeated Insult Dermal Sensitization Study of Altosid Pellets In Guinea Pigs, (EPA Reg. No. 2724-448).

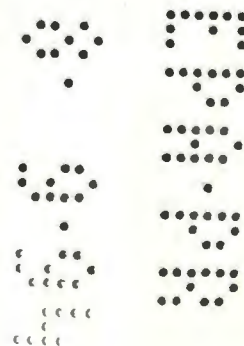
Please contact me at (708)390-3007 if you have any questions.

Yours Sincerely,

**SANDOZ AGRO, INC.**

  
\_\_\_\_\_  
Steven R. Spaulding  
Senior Registration Specialist

cc: R. Garg  
J. Kunstman



## TRANSMITTAL DOCUMENT

### SUBMITTED BY

Sandoz Agro, Inc.  
1300 East Touhy Avenue  
Des Plaines, Illinois 60018

### REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Submission of Acute Toxicity Data to Support Reregistration of Altosid Pellets  
(EPA Reg. No. 2724-448)

### TRANSMITTAL DATE

August 8, 1994

### LIST OF SUBMITTED DOCUMENTS

Volume I: Blaszcak, D.L. (1994). Acute Oral Toxicity Study of Altosid Pellets In Rats, (EPA Reg. No. 2924-448). Pharmacology:LSR Study Number 93-0856. U.S. EPA Pesticide Assessment Guideline (FIFRA) Subdivision F; Section 81-1.

43333801

Volume II: Blaszcak, D.L. (1994). Acute Dermal Toxicity Study of Altosid Pellets in Rabbits, (EPA Reg. No. 2724-448). Pharmacology:LSR Study Number 93-0857. U.S. EPA Pesticide Assessment Guideline (FIFRA) Subdivision F; Section 81-2.

43333802

Volume III: Blaszcak, D.L. (1994). Primary Eye Irritation Study of Altosid Pellets in Rabbits, (EPA Reg. No. 2724-448). Pharmacology:LSR Study Number 93-0859. U.S. EPA Pesticide Assessment Guideline (FIFRA) Subdivision F; Section 81-4.

43333803

Volume IV: Blaszcak, D.L. (1994). Primary Dermal Irritation Study of Altosid Pellets in Rabbits, (EPA Reg. No. 2724-448). Pharmacology: LSR Study Number 93-0858. U.S. EPA Pesticide Assessment Guideline (FIFRA) Subdivision F; Section 81-5.

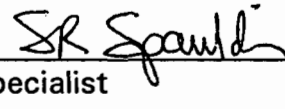
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Volume V: Blaszcak, D.L. (1994). Closed Patch Repeated Insult Dermal Sensitization Study of Altosid Pellets In Guinea Pigs, (EPA Reg. No. 2724-448). Pharmacology: LSR Study Number 93-0860. U.S. EPA Pesticide Assessment Guideline (FIFRA) Subdivision F; Section 81-6.

43333805

COMPANY OFFICIAL:

Steven R. Spaulding  
Senior Registration Specialist



COMPANY NAME:

SANDOZ AGRO, INC.

COMPANY CONTACT:

Steven R. Spaulding (708) 390-3007





# DATA EVALUATION REPORT

## ALTOSID PELLETS

Study Type: DERMAL SENSITIZATION – GUINEA PIG (81-6)

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

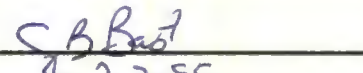
Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory\*  
Oak Ridge, TN 37831  
Task Order No. 95-1

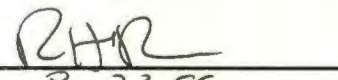
Primary Reviewer:  
C. Scott Jamison, Ph.D.

Signature:   
Date: 8/8/95

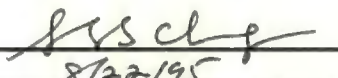
Secondary Reviewers:  
Cheryl B. Bast, Ph.D., D.A.B.T.

Signature:   
Date: 8-23-95

Robert H. Ross, M.S., Group Leader

Signature:   
Date: 8-23-95

Quality Assurance:  
Susan Chang, M.S.

Signature:   
Date: 8/22/95

### Disclaimer

The final Data Evaluation Report may have been altered by the Health Effects Division subsequent to signing by Oak Ridge National Laboratory personnel.

\*Managed by Lockheed Martin Energy Systems, Inc., for the U.S. Department of Energy under Contract No. DE-AC05-84OR21400



27221-445

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

AUG 30 1995

OFFICE OF PREVENTION,  
PESTICIDES AND TOXIC  
SUBSTANCES

**MEMORANDUM**

**SUBJECT:** Review of Acute Mammalian Toxicity Data in Support of Registration of Methoprene End-Use Product, Altosid Pellets, by Sandoz Agro, Inc. (ID # 002724-00448; Barcode D206771; Submission # S472104; Chemical Code Number 105401; Case No. 010616)

**TO:** Willie H. Nelson  
Regulatory Action Leader  
Biopesticides and Pollution Prevention Division (7501W)

**FROM:** Sheryl K. Reilly, Ph.D., Biologist *SKR*  
Biopesticides and Pollution Prevention Division (7501W)

**THRU:** J. Thomas McClintock, Ph.D., Team Leader *JTM*  
Biopesticides and Pollution Prevention Division (7501W)

**ACTION REQUESTED:** Review of six acute mammalian toxicity data in support of the registration of Altosid Pellets.

**CONCLUSIONS:** The studies are summarized as follows:

**MRID NO.: 433338-01 Acute Oral Toxicity - Rat (152-10)**

Sprague-Dawley rats (10/sex) were treated with a single oral dose of Altosid Pellets and observed for 14 days following dosing. Altosid Pellets was prepared for administration by grinding with a mortar and pestle and mixing with distilled water to provide a 500 mg/mL solution. Rats were treated with the 500 mg/mL solution of Altosid Pellets at 10.2 mL/kg (5100 mg/kg) body weight. There were no deaths during the study. Body weights increased for all males over the 14 day observation period. However, 1 female lost weight and 2/5 had no weight gain from days 8 to 15. There were no significant clinical signs during the study, and no significant pathological observations at termination. The oral LD<sub>50</sub> for Altosid Pellets is > 5100 mg/kg body weight for Sprague-Dawley rats. The study is acceptable, and places the test material in Toxicity Category IV.



**MRID NO.: 433338-02 Acute Dermal Toxicity - Rabbit (152-11)**

Six male and five female Hra:(NZW)SPF rabbits were treated with a single dermal dose of Altosid Pellets at 2100 mg/kg body weight for 24 hours and observed for 14 days following treatment. For treatment, Altosid Pellets was ground with a mortar and pestle, added to gauze, and moistened with saline. There was no mortality, severe dermal irritation, adverse clinical signs, and no significant macroscopic pathological findings in the study. Therefore, under the conditions of this study, the dermal LD<sub>50</sub> for Altosid Pellets is greater than 2100 mg/kg body weight for New Zealand White rabbits. This places Altosid Pellets in Toxicity Category III. This study is acceptable.

**MRID NO.: 433338-04 Primary Eye Irritation - Rabbit (152-13)**

Hra:(NZW)SPF rabbits (4 males, 5 females) were treated with a single ocular dose (0.1 cm<sup>3</sup>/eye) of ground, dry Altosid Pellets. The test material was administered into the lower conjunctival sac of the right eye of each animal and the eye held shut for 1 second. The eyes of 3 animals (2 males, 1 female) were washed with lukewarm water 20-30 seconds after dosing. The eyes of the other rabbits and 2/3 rabbits in the washed eyes group were washed 24 hours after dosing to remove remaining residual test material. The left eye of each rabbit served as a control. The eyes of all rabbits were checked for irritation at 1, 24, 48, and 72 hours, 6 and 7 days after dosing or until irritation cleared. Eye irritation for rabbits in the unwashed eyes group at 1 hour post-treatment consisted of mild to severe conjunctivitis and slight iritis, progressing to mild to severe conjunctivitis, slight to moderate iritis, and mild corneal opacity and mild to moderate ulceration at 24 and 48 hours post-treatment. At 72 hours post-treatment, eye irritation consisted of mild or moderate redness and mild chemosis, with no iritis or corneal effects. There was no eye irritation noted at day 7 post-treatment. In the washed eye group, eye irritation consisted of mild to moderate conjunctivitis and slight iritis at 1 hour and mild conjunctivitis at 24 hours post-treatment. Ocular irritation was no longer present in 3/3 rabbits in the washed eye group by 48 hours post-treatment.

Under the conditions of the study, Altosid Pellets are mildly irritating to the eyes of New Zealand White rabbits and the test compound is placed in Toxicity Category III. This study is acceptable.

**MRID NO.: 433338-05 Primary Dermal Irritation - Rabbit (152-14)**

New Zealand white (Hra:(NZW)SPF) rabbits (3 males, 3 females) were treated with a single dermal dose (0.5 g) of Altosid Pellets. The test material was ground, moistened with saline, applied to the shaved backs of the rabbits, covered with gauze, and was removed by wiping 4 hours later. Rabbits were observed at 0.5, 24, 48, and 72 hours after removal of wrapping. There was no erythema and no edema noted in 6/6 rabbits at any timepoint after removal of the wrappings. The primary irritation index was 0.0. There were no clinical signs of toxicity, and no mortality.

As there were no signs of skin irritation at any timepoint after exposure, including 72 hours, Altosid Pellets is not an irritant to the skin of New Zealand white rabbits and is placed in Toxicity Category IV. This study is Acceptable.



**MRID NO.: 433338-06 Dermal Sensitization, Buehler Method - Guinea Pig (152-15)**

Dunkin Hartley albino (Haz:(DH)fBR) guinea pigs (10/sex) were treated with 0.3 cm<sup>3</sup> (moistened with 0.3 mL saline) Altosid Pellets for 6 hours, once per week for 3 weeks. Two weeks after the third exposure, the guinea pigs were challenged with test material applied to a naive skin site. In order to distinguish an irritation reaction from sensitization, an irritation control group (5/sex) of guinea pigs were subjected to the challenge procedure only. A positive control group (5/sex) was subjected to induction with 0.3 mL of 0.005 g/mL dinitrochlorobenzene (DNCB) and to challenge with 0.3 mL of 0.003 g/mL DNCB. An irritation control for DNCB was treated similarly with a challenge dose, but without the induction series. There were no dermal responses to Altosid Pellets after the first induction dose. Dermal responses after challenge with Altosid Pellets consisted of very slight (score = 0.5) erythema at 24 hours in 1 female, and no responses in any of the guinea pigs at 48 hours post-exposure. There was no mortality and no treatment-related effects on body weight gain for males or females. There were no clinical signs of toxicity reported.

Under the conditions of the study, Altosid Pellets did not cause contact sensitization in Dunkin Hartley guinea pigs. This study is **Acceptable**.

The Data Evaluation Reports are attached.

EPA Reviewer: Sheryl Reilly, Ph.D.  
Biopesticides and Pollution Prevention Division (7501W)

SLR  
Date: 8/29/95

## DATA EVALUATION REPORT

STUDY TYPE: Acute Oral Toxicity – Rat (152-10)

CASE NO: 010616

TOX. CHEM. NO: 105401

DP BARCODE: 206771

MRID NO.: 433338-01

TEST MATERIAL: Altosid Pellets

SYNONYMS: Methoprene

STUDY NUMBER: Pharmaco LSR Study Number: 93-0856; Zoecon Study Number: 2032

SPONSOR: Sandoz Agro, Inc., 1300 E. Touhy Avenue, Des Plaines, IL 60018

TESTING FACILITY: Pharmaco LSR, Inc., Toxicology Services North America, P.O. Box 2360, Mettlers Road, East Millstone, New Jersey 08875-2360

TITLE OF REPORT: Acute Oral Toxicity Study of Altosid Pellets in Rats

AUTHOR: Donna L. Blaszcak

REPORT ISSUED: February 25, 1994 (study completion date)

EXECUTIVE SUMMARY: Sprague-Dawley rats (10/sex) were treated with a single oral dose of Altosid Pellets and observed for 14 days following dosing. Altosid Pellets was prepared for administration by grinding with a mortar and pestle and mixing with distilled water to provide a 500 mg/mL solution. Rats were treated with the 500 mg/mL solution of Altosid Pellets at 10.2 mL/kg (5100 mg/kg) body weight.

There were no deaths during the study. Body weights increased for all males over the 14 day observation period. However, 1 female lost weight and 2/5 had no weight gain from days 8 to 15. There were no significant clinical signs during the study, and no significant macroscopic pathological observations at termination.

The oral LD<sub>50</sub> for Altosid Pellets is greater than 5100 mg/kg body weight for Sprague-Dawley rats. This study is Acceptable, and Altosid Pellets are classified in Toxicity Category IV.



## A. MATERIALS

### 1. Test material: Altosid Pellets

Description: dark gray to black pellets with a slight hydrocarbon odor

Lot/Batch No.: 93040101

Purity: responsibility of the sponsor

Stability of compound: responsibility of the sponsor

### 2. Test animals

Species: rat

Strain: Sprague-Dawley CD

Age and weight at study initiation: 9-12 weeks; Pretest (day 0): 305-327 g (males), 217-235 g (females)

Source: Charles River Breeding Laboratories, Inc., Kingston, New York 12484

### 3. Animal care

Housing: individually in suspended, stainless steel cages with wire mesh bottoms

Food: Certified Purina Rodent Diet No. 5002 (Meal), Purina Mills, Inc., St. Louis, MO, *ad libitum*

Water: municipal water supply, automatic watering system, *ad libitum*

Acclimation period: 9 days

Environmental conditions:

Temperature: 68-76°F

Humidity: 52-70%

Photoperiod: 12 hour light/dark cycle

## B. METHODS

After a 20 hour fast, 10 rats (5/sex) were given a single oral dose (5100 mg/kg body weight) administered with a ball-tipped intubation needle fitted to a syringe. The test material was prepared for administration by grinding Altosid Pellets with a mortar and pestle, adding distilled water and mixing with a homogenizer to produce a 500 mg/mL mixture. The test material was prepared a few hours prior to dosing and was again mixed well immediately prior to dosing. The individual doses were determined based upon day 0 (prior to fasting) body weights. Animals were observed at 1, 2, and 4 hours after administration of test material and once daily thereafter for 14 days for general condition, and abnormalities of skin and fur, eyes, nose, oral cavity, abdomen and external genitalia, as well as evaluations of respiration and palpation for tissue masses. Animals were observed twice daily for mortality. Food consumption was not monitored. Body weights were recorded at day 0 (prior to fasting), day 1 (just prior to dosing), and days 8 and 15 (termination). At termination, all surviving animals were euthanized by carbon dioxide inhalation and gross necropsies performed. The macroscopic pathological examination included the external surface, all orifices, the organs and tissues of the cranial, thoracic, abdominal, and pelvic cavities, the neck and the remainder of the carcass. The LD<sub>50</sub> was not calculated using a statistical method as there was no mortality.



## C. RESULTS

### 1. Mortality

There were no deaths during the study. The LD<sub>50</sub> is greater than 5100 mg/kg for males and females.

### 2. Clinical observations

There were no pharmacologic and toxicological abnormalities noted.

### 3. Body weight

Body weight increases from day 0 to day 8, ranged from 43-57 g for males, and from 12-38 g for females. Body weight increases from day 0 to day 15, ranged from 51-80 g for males, and from 24-44 g for females (mean body weight gains were 65.6 g for males and 33.0 g for females). Body weights increased from day 8 to 15 for 5/5 males and 2/5 females. Body weights decreased for 1 female (9 g decrease) and 2 females had weight gains of 0 g from day 8 to 15.

### 4. Necropsy

There were no significant macroscopic pathological observations.

### 5. LD<sub>50</sub>

Under the conditions of this study, the oral LD<sub>50</sub> for Altosid Pellets is greater than 5100 mg/kg body weight for Sprague-Dawley rats. Altosid Pellets are classified in Toxicity Category IV.

*D. Signed and dated Quality Assurance and GLP statements were present.*

## E. STUDY DEFICIENCIES

The study report (MRID No. 433338-01), p. 13, contains a portion of the Methods section for a dermal study. These methods do not apply to an oral study. It is assumed by the reviewer that these statements were inadvertently included in the report, and that the paragraphs that should have been included do not contain information that would change the conclusions of the study report.

# DATA EVALUATION REPORT

## ALTOSID PELLETS

Study Type: ACUTE GAVAGE - RAT (81-1)

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory\*  
Oak Ridge, TN 37831  
Task Order No. 95-1

Primary Reviewer:

C. Scott Jamison, Ph.D.

Signature: C. S. Jamison

Date: 8/8/95

Secondary Reviewers:

Cheryl B. Bast, Ph.D., D.A.B.T.

Signature: C. B. Bast

Date: 8-23-95

Robert H. Ross, M.S., Group Leader

Signature: R. H. Ross

Date: 8-23-95

Quality Assurance:

Susan Chang, M.S.

Signature: S. Chang

Date: 8/22/95

### Disclaimer

The final Data Evaluation Report may have been altered by the Health Effects Division subsequent to signing by Oak Ridge National Laboratory personnel.

\*Managed by Lockheed Martin Energy Systems, Inc., for the U.S. Department of Energy under Contract No. DE-AC05-84OR21400



EPA Reviewer: Sheryl Reilly, Ph.D.  
Biopesticides and Pollution Prevention Division

5142 Date: 8/29/95

### DATA EVALUATION REPORT

STUDY TYPE: Acute Dermal Toxicity - Rabbit (152-11)

CASE NO: 010616

TOX. CHEM. NO: 105401

DP BARCODE: D206771

MRID NO.: 433338-02

TEST MATERIAL: Altosid Pellets

SYNONYMS: Methoprene

STUDY NUMBER: Pharmaco LSR Study No.: 93-0857; Zoecon Study Number: 2033.

SPONSOR: Sandoz Agro, Inc., 1300 E. Touhy Avenue, Des Plaines, IL 60018

TESTING FACILITY: Pharmaco LSR, Inc., Toxicology Services North America, P.O. Box 2360, Mettlers road, East Millstone, New Jersey 08875-2360

TITLE OF REPORT: Acute Dermal Toxicity Study of Altosid Pellets in Rabbits

AUTHOR: Donna L. Blaszcak

REPORT ISSUED: February 25, 1994 (study completion date)

EXECUTIVE SUMMARY: Six male and five female Hra:(NZW)SPF rabbits were treated with a single dermal dose of Altosid Pellets at 2100 mg/kg body weight for 24 hours and observed for 14 days following treatment. For treatment, Altosid Pellets was ground with a mortar and pestle, added to gauze, and moistened with saline.

There was no mortality, severe dermal irritation, adverse clinical signs, and no significant macroscopic pathological findings in the study. Therefore, under the conditions of this study, the dermal LD<sub>50</sub> for Altosid Pellets is greater than 2100 mg/kg body weight for New Zealand White rabbits. This places Altosid Pellets in Toxicity Category III. This study is Acceptable.



## A. MATERIALS

### 1. Test material: Altosid Pellets

Description: dark gray to black pellets with a slight hydrocarbon odor

Lot/Batch No.: 93040101

Purity: responsibility of the sponsor

Stability of compound: responsibility of the sponsor

Active ingredient: not reported

### 2. Test animals

Species: rabbit

Strain: New Zealand White, Hra:(NZW)SPF

Age and weight at study initiation:  $\geq 8$  weeks, 1.9-2.2 kg (males), 2.0-2.3 kg (females)

Source: HRP, Inc., Denver, PA

### 3. Animal care

Housing: individually in suspended, stainless steel cages with wire mesh bottoms

Food: Lab Rabbit Chow HF (Purina #5326)

Water: municipal water supply, automatic watering system, *ad libitum*

Acclimation period: 15 days for 6 males, 4 females; 30 days for 1 female

Environmental conditions:

Temperature: 62-73°F

Humidity: 36-70%

Photoperiod: 12 hour light/dark cycle

## B. METHODS

All animals had body weights within 20% of the mean for each sex, and were considered suitable for use in the study based upon pretest physical examinations. The hair on the dorsal surface and sides from the scapula to the pelvic area on each of six male and five female NZW rabbits was clipped with electric clippers 24 hours prior to dosing. At least 10% of the total body surface on each animal (12 cm x 14 cm) was exposed and no abrasions were noted. Altosid Pellets were prepared for administration by grinding with a mortar and pestle. The dry test material (2100 mg/kg body weight) was placed onto a 4 inch x 12 inch strip of 8-ply gauze and moistened with 1 mL of saline. The gauze was wrapped around the trunk of the animal, covering the application site. An impervious plastic sleeve was wrapped over the gauze and secured with Elastoplast tape, in order to contain the test material without leakage or undue pressure. Elizabethan collars were placed on all animals in order to prevent ingestion of the test material or disruption of the wrappings.

The bandaging was removed after 24 hours, and the test site wiped free of excess test material with distilled water and gauze. Animals were observed for signs of toxicity at 1, 2, and 4 hours after test material application and daily thereafter for 14 days for severe

dermal effects, general condition, and for abnormalities of skin and fur, eyes, nose, oral cavity, abdomen and external genitalia as well as evaluations of respiration and palpation for tissue masses. Mortality observations were performed twice daily. Body weights were determined at days 0 (prior to clipping), 1 (prior to dosing), 8, and 15 (termination). Day 0 body weights were used to calculate the doses. All animals were euthanized at day 15 by an intravenous overdose of sodium pentobarbital and subjected to gross pathological examination of the external surface, all orifices, the organs and tissues of the cranial, thoracic, abdominal and pelvic cavities and neck and the remainder of the carcass. Food consumption data was not reported.

The LD<sub>50</sub> was not calculated using statistical analysis as there was no mortality. The dermal exposures to Altosid Pellets at 2100 mg/kg corresponded to 25.6 mg/cm<sup>2</sup> for males and 26.75 mg/cm<sup>2</sup> for females (calculated by the reviewer). One female was found to be a male on gross pathological examination. Another female was then subjected to treatment with Altosid Pellets as described approximately 1 month after necropsy of the initial test group.

### C. RESULTS

#### 1. Mortality

There was no mortality during the 14-day observation period.

#### 2. Clinical Observations

There were no treatment-related clinical signs.

#### 3. Body Weight

Body weight gains ranged from -0.2 to 0.2 kg for males and for females.

#### 4. Necropsy

The gross pathological findings consisted of mild discoloration, mild enlargement, severed dilatation, and abnormal contents (moderate) of the kidney of 1 male. These findings are not toxicologically significant. There were no gross pathological findings for the other males (5/6) or for the females (5/5) treated dermally with Altosid Pellets.

#### 5. LD<sub>50</sub>

The dermal LD<sub>50</sub> for Altosid Pellets is greater than 2100 mg/kg body weight for New Zealand White rabbits. Based upon the LD<sub>50</sub>, Altosid Pellets is classified in Toxicity Category III. This study is classified as Acceptable.

D. Signed and dated Quality Assurance and GLP statements were present.



# DATA EVALUATION REPORT

## ALTOSID PELLETS

Study Type: ACUTE DERMAL - RABBIT (81-2)

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory\*  
Oak Ridge, TN 37831  
Task Order No. 95-1

Primary Reviewer:

C. Scott Jamison, Ph.D.

Signature: C. S. Jamison

Date: 8/8/95

Secondary Reviewers:

Cheryl B. Bast, Ph.D., D.A.B.T.

Signature: C. B. Bast

Date: 8-23-95

Robert H. Ross, M.S., Group Leader

Signature: R. H. Ross

Date: 8-23-95

Quality Assurance:

Susan Chang, M.S.

Signature: S. Chang

Date: 8/22/95

### Disclaimer

The final Data Evaluation Report may have been altered by the Health Effects Division subsequent to signing by Oak Ridge National Laboratory personnel.

\*Managed by Lockheed Martin Energy Systems, Inc., for the U.S. Department of Energy under Contract No. DE-AC05-84OR21400



EPA Reviewer: Sheryl Reilly, Ph.D.  
Biopesticides and Pollution Prevention Division (7501W)

5/4  
Date: 8/29/91

## DATA EVALUATION REPORT

STUDY TYPE: Primary Eye Irritation-Rabbit (152-13)

CASE NO: 010616

TOX. CHEM. NO: 105401

DP BARCODE: D206771

MRID NO.: 433338-03

TEST MATERIAL: Altosid Pellets

SYNONYMS: Methoprene

STUDY NUMBER: Pharmaco LSR Study No.: 93-0859; Zoecon Study Number: 2035

SPONSOR: Sandoz Agro, Inc., 1300 E. Touhy Avenue, Des Plaines, IL 60018

TESTING FACILITY: Pharmaco LSR, Inc., Toxicology Services North America, P.O. Box 2360, Mettlers road, East Millstone, New Jersey 08875-2360

TITLE OF REPORT: Primary Eye Irritation Study of Altosid Pellets in Rabbits

AUTHOR: Donna L. Blaszcak

REPORT ISSUED: February 25, 1994 (study completion date)

EXECUTIVE SUMMARY: Hra:(NZW)SPF rabbits (4 males, 5 females) were treated with a single ocular dose (0.1 cm<sup>3</sup>/eye) of ground, dry Altosid Pellets. The test material was administered into the lower conjunctival sac of the right eye of each animal and the eye held shut for 1 second. The eyes of three rabbits (2 males, 1 female) were washed with lukewarm water 20-30 seconds after dosing. The treated eyes of 6/6 rabbits in the unwashed eyes group and 2/3 rabbits in the washed eyes group were washed 24 hours after dosing to remove remaining residual test material. The left eye of each rabbit served as a control. The eyes of all rabbits were checked for irritation at 1, 24, 48, and 72 hours, 6 and 7 days after dosing or until irritation cleared.

Eye irritation for rabbits in the unwashed eyes group at 1 hour post-treatment consisted of mild to severe conjunctivitis and slight iritis, progressing to mild to severe conjunctivitis, slight to moderate iritis, and mild corneal opacity and mild to moderate ulceration at 24 and 48 hours post-treatment. At 72 hours post-treatment, eye irritation consisted of conjunctivitis (mild (3/6) or moderate (1/6) redness and mild (2/6) chemosis), with no iritis

or corneal effects. There was no eye irritation noted at day 7 post-treatment for 6/6 rabbits. In the washed eye group, eye irritation consisted of mild to moderate conjunctivitis and slight iritis at 1 hour and mild conjunctivitis at 24 hours post-treatment. Ocular irritation was no longer present in 3/3 rabbits in the washed eye group by 48 hours post-treatment.

As there were corneal effects (opacity and ulceration) at 24 and 48 hours post-treatment and because conjunctivitis was present at 1, 24, 48, and 72 hours, and 6 days post-treatment, but the irritation cleared within 7 days, **Altosid Pellets is classified as a mild irritant** to the eyes of male and female New Zealand White rabbits and is placed in **Toxicity Category III**. This study is **Acceptable**.

#### A. MATERIALS

##### 1. Test material: Altosid Pellets

Description: dark gray to black pellets with a slight hydrocarbon odor

Lot/Batch No.: 93040101

Purity: responsibility of the sponsor

Stability of compound: responsibility of the sponsor

Active ingredient: not reported

pH: not reported

##### 2. Test animals

Species: rabbit

Strain: New Zealand White, Hra:(NZW)SPF

Age and weight at study initiation:  $\geq 8$  weeks; 2.0-2.4 kg

Source: HRP, Inc., Denver, PA

##### 3. Animal care

Housing: individually in suspended stainless steel cages with wire mesh bottoms

Food: Lab Rabbit Chow HF (Purina No. 5326)

Water: municipal water supply, automatic watering system, *ad libitum*

Acclimation period: 15 days

Environmental conditions:

Temperature: 63-70°F

Humidity: 44-74%

Photoperiod: 12 hour light/dark cycle

#### B. METHODS

Each rabbit (5 males, 4 females) was treated with a single dose ( $0.1 \text{ cm}^3$ ) of Altosid Pellets, which were ground with a mortar and pestle prior to administration. Both eyes of each animal were examined on the day before dosing using fluorescein dye to check for corneal ulceration and on the day of dosing (without dye). Only animals negative for corneal ulceration, conjunctival injury, or irritation were used in the study. The test material was introduced into the lower conjunctival sac of the right eye of each animal and the eyelids



held shut for 1 second to prevent loss of material. The left eye served as a control. After 20-30 seconds, the eyes of 3 rabbits (2 males, 1 female) were washed for approximately 1 minute with lukewarm water. The eyes of the remaining six rabbits (3 males, 3 females) were left unwashed. After 24 hours, the eyes of all 8/9 animals were rinsed to remove residual test material.

The eyes of all animals were examined at approximately 1, 24, 48, and 72 hours, 6 and 7 days after treatment. At each timepoint, treated eyes were examined and scored for ocular reactions in comparison to the untreated eyes. Ocular reactions were scored for the conjunctivae (redness, chemosis, discharge, and white tissue or ulceration), the iris, and the cornea (opacity, area of corneal involvement, stippling, and ulceration). Fluorescein dye was used to confirm the presence or absence of corneal ulceration, starting at the 24 hour examination. Eye examinations with fluorescein dye continued until there was no dye retention for 2 observations. Irritation was defined as the production of reversible changes. Eye corrosion was defined as the production of irreversible tissue damage to the eye following test material administration. Observations for mortality or clinical signs of toxicity were performed twice daily. There were no body weight changes reported by the study authors. At the termination of the study, all rabbits were euthanized with sodium pentobarbital. There was no macroscopic examination of tissues.

### C. RESULTS

The incidence of eye irritation is presented in Table 1, below. There was conjunctivitis present in males and females in the unwashed eyes group at 1, 24, 48, and 72 hours, and 6 days post-treatment, iritis present at 1 and 24 hours post-treatment, and corneal effects consisting of slight or mild opacity and mild or moderate ulceration at 1, 24, and 48 hours post-treatment. All irritation cleared by 7 days post-treatment.

For the washed eye group (2 males, 1 female), irritation consisted of mild to moderate conjunctivitis and slight iritis, at 1 hour post-treatment, and mild redness (2/3) at 24 hours post-treatment. There was no eye irritation observed at 48 or 72 hours post-treatment. Residual test material was present in the eyes of 3/3 rabbits at 1 hour, 2/3 rabbits at 24 hours, and 1/3 rabbits at 48 hours post-treatment, indicating that the 1 minute wash after administration of the test material was insufficient to remove the material from the eye. However, the severity of the irritation was reduced by the washing procedure.

The maximum mean irritation score (14.5) was obtained for rabbits in the unwashed eyes group at 24 hours post-treatment. Altosid Pellets is classified as a mild eye irritant in New Zealand white rabbits and is in Toxicity Category III.

D. Signed and dated Quality Assurance and GLP statements were present.

TABLE 1. INCIDENCE OF OCULAR IRRITATION IN MALE AND  
FEMALE NEW ZEALAND WHITE RABBITS TREATED WITH ALTOSID PELLETS



held shut for 1 second to prevent loss of material. The left eye served as a control. After 20-30 seconds, the eyes of 3 rabbits (2 males, 1 female) were washed for approximately 1 minute with lukewarm water. The eyes of the remaining six rabbits (3 males, 3 females) were left unwashed. After 24 hours, the eyes of all 8/9 animals were rinsed to remove residual test material.

The eyes of all animals were examined at approximately 1, 24, 48, and 72 hours, 6 and 7 days after treatment. At each timepoint, treated eyes were examined and scored for ocular reactions in comparison to the untreated eyes. Ocular reactions were scored for the conjunctivae (redness, chemosis, discharge, and white tissue or ulceration), the iris, and the cornea (opacity, area of corneal involvement, stippling, and ulceration). Fluorescein dye was used to confirm the presence or absence of corneal ulceration, starting at the 24 hour examination. Eye examinations with fluorescein dye continued until there was no dye retention for 2 observations. Irritation was defined as the production of reversible changes. Eye corrosion was defined as the production of irreversible tissue damage to the eye following test material administration. Observations for mortality or clinical signs of toxicity were performed twice daily. There were no body weight changes reported by the study authors. At the termination of the study, all rabbits were euthanized with sodium pentobarbital. There was no macroscopic examination of tissues.

#### C. RESULTS

The incidence of eye irritation is presented in Table 1, below. There was conjunctivitis present in males and females in the unwashed eyes group at 1, 24, 48, and 72 hours, and 6 days post-treatment, iritis present at 1 and 24 hours post-treatment, and corneal effects consisting of slight or mild opacity and mild or moderate ulceration at 1, 24, and 48 hours post-treatment. All irritation cleared by 7 days post-treatment.

For the washed eye group (2 males, 1 female), irritation consisted of mild to moderate conjunctivitis and slight iritis, at 1 hour post-treatment, and mild redness (2/3) at 24 hours post-treatment. There was no eye irritation observed at 48 or 72 hours post-treatment. Residual test material was present in the eyes of 3/3 rabbits at 1 hour, 2/3 rabbits at 24 hours, and 1/3 rabbits at 48 hours post-treatment, indicating that the 1 minute wash after administration of the test material was insufficient to remove the material from the eye. However, the severity of the irritation was reduced by the washing procedure.

The maximum mean irritation score (14.5) was obtained for rabbits in the unwashed eyes group at 24 hours post-treatment. Altosid Pellets is classified as a mild eye irritant in New Zealand white rabbits and is in Toxicity Category III.

D. Signed and dated Quality Assurance and GLP statements were present.

**TABLE 1. INCIDENCE OF OCULAR IRRITATION IN MALE AND  
FEMALE NEW ZEALAND WHITE RABBITS TREATED WITH ALTOSID PELLETS**

Time Post-Treatment	Cornea		Iritis	Conjunctivitis			Mean Eye Irritation Score
	Opacity	Ulceration		Redness	Chemosis	Discharge	
Unwashed Eyes							
1 Hour	0/6	0/6	3/6	6/6	6/6	6/6	8.5
24 Hour	5/6	6/6	4/6	6/6	6/6	4/6	14.5
48 Hour	0/6	1/6	0/6	6/6	5/6	2/6	4.3
72 Hour	0/6	0/6	0/6	4/6	2/6	0/6	2.0
Day 6	0/2	0/2	0/2	1/2	0/2	0/6	1.0
Washed Eyes							
1 Hour	0/3	0/3	2/3	3/3	2/3	3/3	8.7
24 Hour	0/3	0/3	0/3	2/3	0/3	0/3	1.3
48 Hour	0/3	0/3	0/3	0/3	0/3	0/3	0.0
72 Hour	0/3	0/3	0/3	0/3	0/3	0/3	0.0

Data adapted from Tables I and II, pp. 21-25, MRID No. 433338-03.



# DATA EVALUATION REPORT

## ALTOSID PELLETS

Study Type: PRIMARY EYE IRRITATION - RABBIT (81-4)

Prepared for

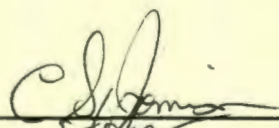
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory\*  
Oak Ridge, TN 37831  
Task Order No. 95-1

Primary Reviewer:

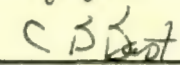
C. Scott Jamison, Ph.D.

Signature: 

Date: 8/8/95

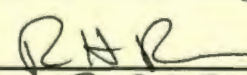
Secondary Reviewers:

Cheryl B. Bast, Ph.D., D.A.B.T.

Signature: 

Date: 8-23-95

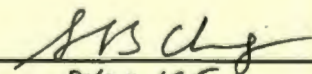
Robert H. Ross, M.S., Group Leader

Signature: 

Date: 8-23-95

Quality Assurance:

Susan Chang, M.S.

Signature: 

Date: 8/22/95

### Disclaimer

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\*Managed by Lockheed Martin Energy Systems, Inc., for the U.S. Department of Energy under Contract No. DE-AC05-84OR21400



EPA Reviewer: Sheryl Reilly, PhD.  
Biopesticides and Pollution Prevention Division (7501W)

SLR Date: 8/29/95

### DATA EVALUATION REPORT

STUDY TYPE: Primary Skin Irritation - Rabbit (152-14)

CASE NO: 010616

TOX. CHEM. NO: 105401

DP BARCODE: D206771

MRID NO: 433338-04

TEST MATERIAL: Altosid Pellets

SYNONYMS: Methoprene

STUDY NUMBER: Pharmaco LSR Study Number: 93-0858; Zoecon Study Number: 2034

SPONSOR: Sandoz Agro, Inc., 1300 E. Touhy Avenue, Des Plaines, IL 60018

TESTING FACILITY: Pharmaco LSR, Inc., Toxicology Services North America, P.O. Box 2360, Mettlers road, East Millstone, New Jersey 08875-2360

TITLE OF REPORT: Primary Dermal Irritation Study of Altosid Pellets in Rabbits

AUTHOR: Donna L. Blaszcak

REPORT ISSUED: February 25, 1994 (study completion date)

EXECUTIVE SUMMARY: New Zealand white (Hra:(NZW)SPF) rabbits (3 males, 3 females) were treated with a single dermal dose (0.5 g) of Altosid Pellets. The test material was ground, moistened with saline, applied to the shaved backs of the rabbits, covered with gauze, and was removed by wiping 4 hours later. Rabbits were observed at 0.5, 24, 48, and 72 hours after removal of wrapping.

There was no erythema and no edema noted in 6/6 rabbits at any timepoint after removal of the wrappings. The primary irritation index was 0.0. There were no clinical signs of toxicity, and no mortality.

As there were no signs of skin irritation at any timepoint after exposure, including 72 hours, Altosid Pellets is not an irritant to the skin of New Zealand white rabbits and is placed in Toxicity Category IV. This study is Acceptable.

## A. MATERIALS

### 1. Test material: Altosid Pellets

Description: dark gray to black pellets with a slight hydrocarbon odor

Lot/Batch No.: 93040101

Purity: responsibility of the sponsor

Stability of compound: responsibility of the sponsor

Active ingredient: not reported

pH: not reported

### 2. Test animals

Species: rabbit

Strain: New Zealand White, Hra:(NZW)SPF

Age and weight at study initiation:  $\geq$  8 weeks, 2.1-2.5 kg

Source: HRP, Inc., Denver, PA

### 3. Animal care

Housing: individually in suspended, stainless steel cages with wire mesh bottoms

Food: Lab Rabbit Chow HF (Purina #5326)

Water: municipal water supply, automatic watering system, *ad libitum*

Acclimation period: 7 days

Environmental conditions:

Temperature: 66-70°F

Humidity: 52-62%

Photoperiod: 12 hour light/dark cycle

## B. METHODS

Each of six rabbits (3/sex) was treated dermally for 4 hours with a single dose (0.5 g) of Altosid Pellets. Approximately 24 hours prior to application, the hair of each animal was clipped with an electric clipper to expose the back from the scapular to the lumbar region, and the skin was examined for abrasions (none were noted in any of the rabbits). The test material was ground with a mortar and pestle, and 0.5 g moistened with 0.5 mL of saline and applied directly to the backs of the rabbits. The test site was covered with gauze (1 inch x 1 inch, approximately 6 cm<sup>2</sup>), held in place with tape. Gauze was then wrapped around each animal to hold the test material in place without undue pressure (semi-occlusive pressure). Elizabethan collars were used to restrain the animals during dosing to prevent disruption of the wrappings and ingestion of the test material. After 4 hours of exposure, wrappings were removed and the test site gently wiped free of excess material with gauze and distilled water. Dermal observations were made approximately 0.5, 24, 48, and 72 hours after removal of wrappings. The test site was examined for the presence of erythema, edema, or other evidence of dermal irritation, such as necrosis, eschar, other irreversible alteration of tissue structures, or other dermal abnormalities. Adjacent areas of untreated skin were used as controls. Any abnormal clinical signs of toxicity were noted. Mortality



checks were performed twice daily. At study termination, all rabbits were euthanized with an intravenous overdose of sodium pentobarbital. There was no gross necropsy performed.

C. RESULTS

For the rabbits (4 males, 2 females) treated dermally with Altosid Pellets, there was no erythema, edema, or other skin irritation evident at 0.5, 24, 48, or 72 hours after removal of wrappings. There were no clinical signs of toxicity reported. Body weight changes, if any, were not reported. No animals died during the study.

At 72 hours post-treatment, there was no skin irritation observable in males or females; thus, Altosid Pellets is placed in Toxicity Category IV.

D. Signed and dated Quality Assurance and GLP statements were present.



# DATA EVALUATION REPORT

## ALTOSID PELLETS

Study Type: PRIMARY SKIN IRRITATION – RABBIT (81-5)

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory\*  
Oak Ridge, TN 37831  
Task Order No. 95-1

Primary Reviewer:

C. Scott Jamison, Ph.D.

Signature: C. S. Jamison

Date: 8/8/95

Secondary Reviewers:

Cheryl B. Bast, Ph.D., D.A.B.T.

Signature: C. B. Bast

Date: 8-22-95

Robert H. Ross, M.S., Group Leader

Signature: R. H. Ross

Date: 8-23-95

Quality Assurance:

Susan Chang, M.S.

Signature: S. S. Chang

Date: 8/22/95

### Disclaimer

The final Data Evaluation Report may have been altered by the Health Effects Division subsequent to signing by Oak Ridge National Laboratory personnel.

\*Managed by Lockheed Martin Energy Systems, Inc., for the U.S. Department of Energy under Contract No. DE-AC05-84OR21400

EPA Reviewer: Sheryl Reilly, Ph.D.  
Biopesticides and Pollution Prevention Division (7501W)

SLR  
Date: 8/28/95

## DATA EVALUATION REPORT

STUDY TYPE: Dermal Sensitization, Buehler Method - Guinea Pig (152-15)

CASE NO: 010616

TOX. CHEM. NO: 105401

DP BARCODE: D206771

MRID NO.: 433338-05

TEST MATERIAL: Altosid Pellets

SYNONYMS: Methoprene

STUDY NUMBER: Pharmaco LSR Study Number: 93-0860; Zoecon Study Number: 2036

SPONSOR: Sandoz Agro, Inc., 1300 E. Touhy Avenue, Des Plaines, IL 60018

TESTING FACILITY: Pharmaco LSR, Inc., Toxicology Services North America, P.O. Box 2360, Mettlers road, East Millstone, New Jersey 08875-2360

TITLE OF REPORT: Closed Patch Repeated Insult Dermal Sensitization Study of Altosid Pellets in Guinea Pigs.

AUTHOR: Donna L. Blaszcak

REPORT ISSUED: March 16, 1994 (study completion date)

EXECUTIVE SUMMARY: Dunkin Hartley albino (Haz:(DH)fBR) guinea pigs (10/sex) were treated with 0.3 cm<sup>3</sup> (moistened with 0.3 mL saline) Altosid Pellets for 6 hours, once per week for 3 weeks. Two weeks after the third exposure, the guinea pigs were challenged with test material applied to a naive skin site. In order to distinguish an irritation reaction from sensitization, an irritation control group of 5 male and 5 female guinea pigs were subjected to the same challenge procedures, but without the induction regimen. A positive control group (5/sex) was subjected to induction with 0.3 mL of 0.005 g/mL dinitrochlorobenzene (DNCB; dissolved in ethanol) and to challenge with 0.3 mL of 0.003 g/mL (dissolved in acetone) DNCB. An irritation control for DNCB was treated similarly with a challenge dose, but without the induction series.

All of the guinea pigs (10/10) treated dermally with DNCB exhibited appropriate skin irritation reactions after the first induction dose and after challenge. There were no dermal responses to Altosid Pellets after the first induction dose. Dermal responses after challenge



with Altosid Pellets consisted of very slight (score = 0.5) erythema at 24 hours in 1 female, and no responses in any of the guinea pigs at 48 hours post-exposure. For Altosid Pellets, the Incidence Index of Sensitization at 24 hours was 0% for the challenge and irritation control groups, and the Severity Indices at 24 hours and 48 hours were 0.025 and 0.0, respectively. There was no mortality and no treatment-related effects on body weight gain for males or females. There were no clinical signs of toxicity reported.

Under the conditions of the study, Altosid Pellets did not cause contact sensitization in Dunkin Hartley guinea pigs. This study is Acceptable.

#### A. MATERIALS

##### 1. Test material: Altosid Pellets

Description: dark gray to black solid with a slight hydrocarbon odor

Lot/Batch No.: 93040101

Purity: responsibility of the sponsor

Stability of compound: responsibility of the sponsor

Active ingredient: not reported

pH: not reported

Density: not reported

##### 2. Test animals

Species: guinea pigs

Strain: albino, Dunkin Hartley; Haz:(DH)fBR

Age and weight at study initiation: 5-6 weeks; 312-440 g (males), 318-435 g (females)

Source: HRP, Inc., Denver, PA

##### 3. Animal care

Housing: individually in suspended, stainless steel cages with wire mesh bottoms

Food: Agway Prolab Guinea Pig Diet, *ad libitum*

Water: municipal water supply, automatic watering system, *ad libitum*

Acclimation period: 16 days

Environmental conditions:

Temperature: 64-75°F

Humidity: 30-80%

Photoperiod: 12 hour light/dark cycle

#### B. METHODS

##### 1. Mortality, clinical signs, and body weights

Mortality checks were performed twice daily. Checks for general health were performed prior to treatment and once weekly and any abnormalities noted. Body weights were determined on the day prior to the first induction and at termination (2 days after challenge). Dermal responses were scored for erythema (scale: 0, no



reaction; 0.5, very slight; 1, slight; 2, moderate; 3, severe), edema, necrosis, and eschar.

## 2. Preliminary irritation study

An initial screening was performed in order to determine the irritancy of the test material. The hair was clipped short on the back and sides the guinea pigs on the day prior to the application of the test material. Altosid Pellets was ground with a mortar and pestle and applied topically to 6 guinea pigs at 100% (0.3 cm<sup>3</sup> in 0.3 mL saline), 50%, 25%, and 10% concentrations (w/v, diluted into distilled water). The test material mixtures were applied to each guinea pig beneath a Hilltop Chamber<sup>®</sup> in a volume of 0.3 mL. The chamber was occluded with overlapping, impermeable plastic and secured with an elastic adhesive bandage (Elastoplast<sup>®</sup>) wound around the torsos of the guinea pigs. The chambers were left in place for 6 hours, then removed and the skin wiped free of excess material with distilled water and gauze. Skin irritation observations were made at 24 and 48 hours.

## 3. Induction

Twenty guinea pigs (10 males, 10 females) were used for testing dermal sensitization of Altosid Pellets. Ten guinea pigs (5 males, 5 females) were used in the positive control group (DNCB). Altosid Pellets was ground with a mortar and pestle and 0.3 cm<sup>3</sup> moistened with 0.3 mL of saline. DNCB was dissolved in 80% ethanol to produce a 0.005 g/mL solution. The hair on the application site (back and sides) of was clipped short with an electric clipper on the day prior to each application. A Hilltop Chamber<sup>®</sup> was saturated with test material (0.3 cm<sup>3</sup> of Altosid Pellets in 0.3 mL saline or 0.3 mL of 0.005 g/mL DNCB). The test site was on the right side of the midline. The chamber was covered by overlapping impermeable plastic, held in place with Elastoplast<sup>®</sup> adhesive elastic bandage wound around the torso of the guinea pig. The chamber was left in place for 6 hours, then removed and the skin wiped free of excess material with distilled water and gauze. Induction was performed once a week, for 3 weeks. Dermal evaluations were made at 24 and 48 hours after the first induction exposure to confirm that a slightly irritating concentration of DNCB was used, and that an appropriate concentration of Altosid Pellets had been chosen.

## 4. Challenge

Fourteen days after the last induction exposure, the test material was administered at a site on the opposite side of the midline from the induction exposure test site. The method for the challenge exposure was the same as was used during the induction exposures, except that the dose of the positive control, DNCB, was lower (0.3 mL of 0.003 g/mL), and the solution used for dissolving DNCB was acetone, rather than ethanol. The dermal response was evaluated 24 and 48 hours after challenge treatment. The results were evaluated by the amount of erythema at the challenge site relative to irritation controls. Two indices were calculated to assess the dermal responses: incidence and severity. The incidence index is the number of animals with a response grade of  $\geq 1$  (at 24 or 48 hours) out of the total number of animals in the group. The severity index for the 24 and 48 hour response reading was determined by dividing the



sum total of the irritation grades in a group by the total number of animals exposed. At study termination, all guinea pigs were euthanized by carbon dioxide inhalation. There was no gross necropsy performed.

## C. RESULTS

### 1. Mortality, clinical signs, and body weights

There was no mortality. The guinea pigs were in good general health at each of the weekly observations. Body weights increased for males and females throughout the post-treatment observation period. Body weight gains for guinea pigs treated with Altosid Pellets ranged from 169-300 g for males, and from 131-219 g for females. These ranges of body weight gains were similar to those for the positive control (174-263 g for males, 123-186 g for females) and the negative/irritation control (187-292 g for males, 100-205 g for females).

### 2. Preliminary irritation study

The preliminary skin irritancy test results indicated that Altosid Pellets applied at 10%, 25%, or 50% was non-irritating to guinea pigs. For Altosid Pellets applied at 100%, very slight erythema was noted for 1 male at 24 hours, and there were no skin irritation reactions observed for 2/3 males and 3/3 females at either the 24 or 48 hour timepoints. There were no other clinical signs of toxicity reported. Altosid Pellets was used undiluted (100%) in the induction and challenge portions of the dermal sensitization test.

### 3. Induction

At the first induction with Altosid Pellets, there were no dermal responses for 20/20 guinea pigs at either 24 or 48 hours. All 10 guinea pigs treated with DNCB exhibited appropriate dermal responses at the first induction. Dermal responses for DNCB or for Altosid Pellets were only recorded by the study authors for the first induction exposure.

### 4. Challenge

Dermal responses for guinea pigs challenged with Altosid Pellets were not suggestive of an irritation or sensitization response. There was very slight erythema for 1 female at 24 hours after challenge. There were no dermal responses in 20/20 guinea pigs at 48 hours after challenge. The Incidence Index of Sensitization to Altosid Pellets at 24 hours was 0%. The Severity Indices at 24 and 48 hours were 0.025 and 0.0, respectively. For irritation controls treated with Altosid Pellets, there were no dermal responses in 10/10 guinea pigs. The Incidence Index of Sensitization at 24 hours was 0% for the irritation control group. The Severity Indices for the irritation control group were 0.0 and 0.0, at 24 and 48 hours, respectively. All 10 guinea pigs exhibited appropriate dermal responses to challenge with DNCB.

# DATA EVALUATION REPORT

## ALTOSID PELLETS

Study Type: DERMAL SENSITIZATION - GUINEA PIG (81-6)

Prepared for

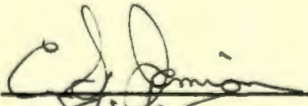
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Crystal Station I  
2800 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Biomedical and Environmental Information Analysis Section  
Health Sciences Research Division  
Oak Ridge National Laboratory\*  
Oak Ridge, TN 37831  
Task Order No. 95-1

Primary Reviewer:

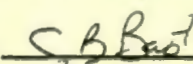
C. Scott Jamison, Ph.D.

Signature: 

Date: 8/8/95

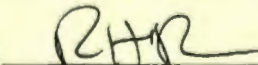
Secondary Reviewers:

Cheryl B. Bast, Ph.D., D.A.B.T.

Signature: 

Date: 8-23-95

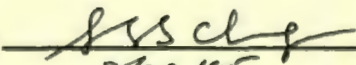
Robert H. Ross, M.S., Group Leader

Signature: 

Date: 8-23-95

Quality Assurance:

Susan Chang, M.S.

Signature: 

Date: 8/22/95

### Disclaimer

The final Data Evaluation Report may have been altered by the Health Effects Division subsequent to signing by Oak Ridge National Laboratory personnel.

\*Managed by Lockheed Martin Energy Systems, Inc., for the U.S. Department of Energy under Contract No. DE-AC05-84OR21400



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FILE

MAY 10 1995

674  
1241

Ms. Ada M. Breaux  
Sandoz Agro, Inc.  
1300 East Touhy Avenue  
Des Plaines, Illinois 60018

Dear Ms. Breaux:

Subject: Zoecon RF-330 Altosid Pellets  
(Removal of Fish Habitat)  
EPA Reg. Number 2724-448  
Your submission of June 14, 1993

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, **is not acceptable**, for the reasons given below.

Sandoz's amendment request of the above date is been denied because, the data originally submitted under MRID No's. 428373-01, 428373-02 and 428373-03, and the supplementary information submitted on March 21, 1995, have been reviewed, and it was determined to be insufficient to meet the requirements for removal of the "Fish habitat" statement from the label of this product and the labels other similar products. Please find attached, copies of the reviews which influenced our decision in denying Sandoz's request.

It is the Biopesticides and Pollution Prevention Division's (BPPD) opinion that the study submitted cannot be used to assess environmental concentrations of methoprene in aquatic organisms since: (1) The results obtained from a microcosm study cannot be extrapolated to be used under typical field Assessment Guidelines (EPA-540/o-85-001) for calculating estimates of environmental concentrations of pesticides in aquatic environments. Therefore,

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

-2-

BPPD cannot recommend removal of the "Fish habitat" restriction for the product labeling at this time, because the results of the fish early life cycle study have triggered the need for a FULL-LIFE CYCLE STUDY (Guideline 72-5). BPPD cannot conduct a chronic risk assessment until such a study is available.

Sincerely,

Janet L. Andersen, Acting Director  
Biopesticides and Pollution Prevention  
Division

WNelson:5\16\95:2724-448:methoprene

CONCURRENCES

SYMBOL							
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 10 1995

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Janet L. Andersen, Acting Director  
Biopesticides and Pollution Prevention  
Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

SEP 21 1992

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Registrant Response To The Methoprene RED 90-Day DCI: Data Waivers And Time Extension Requests. The products involved are as follows:

EPA 2724-337  
EPA 2724-338  
EPA 2724-352  
EPA 2724-375  
EPA 2724-377  
EPA 2724-384  
EPA 2724-393  
EPA 2724-420  
EPA 2724-421  
EPA 2724-427  
EPA 2724-441  
EPA 2724-442  
EPA 2724-446  
EPA 2724-448

To: Phil Hutton (PM 18)  
Attn: Willie Nelson  
Insecticide & Rodenticide Br.  
Registration Division (H7505C)

From: Van M. Seabaugh *GMS 9-21-92*  
Precautionary Review Section  
Registration Support Br.  
Registration Division (H7505C)

Thru: Thomas Ellwanger, Jr. *Thomas C. Ellwanger, Jr.*  
Head, Precautionary Review Section  
Registration Support Br.  
Registration Division (H7505C)

Request

Respond to the registrant's response to the methoprene Reregistration Eligibility Document (RED) 90-day Data Call In (DCI).



Response

I. Submitted to the Agency are two types of waiver requests involving five products.

1. A waiver is requested by the registrant for all acute toxicity studies based on data previously reviewed by the Agency and available in the scientific literature. The products involved are EPA 2724-377 and EPA 2724-384.

PRS Response: We recommend that the waiver request be denied.

In the methoprene RED (March 1991), it is stated that the Agency needs no additional acute toxicity data for methoprene (technical): oral toxicity (Toxicity Category IV); dermal toxicity (Toxicity Category III); inhalation toxicity (Toxicity Category IV); eye irritation (Toxicity Category IV); dermal irritation (Toxicity Category IV); hypersensitivity - a) A guinea pig test using intradermal injections of undiluted test material indicated a positive response. b) Another group of guinea pigs received a topical application, and the results indicated a negative response. c) In addition, the data indicated that methoprene is not a skin sensitizer when humans were tested.

Acute toxicity data are available for methoprene (technical), but the data for the straight chemical cannot be applied to a mixture of chemicals. It becomes a guesstimate to predict the outcome without testing the mixture.

2. A waiver is requested by the registrant for all acute toxicity studies based on valid data previously reviewed by the Agency and product formulation, physical characteristics, and use patterns. The products involved are EPA 2724-375 (briquet), EPA 2724-421 (briquet), and EPA 2724-448 (pellet).

PRS Response

The PRS recommends that a waiver be granted for only the inhalation studies based on formulations, physical characteristics, and use patterns. Anticipated human inhalation exposure and toxicity potential from these products (briquets and pellets) would be expected to be insignificant. However, the PRS recommends denial of the request for the other acute toxicity waivers, because the products have no acute toxicity data for the mixtures. Data are needed for precautionary labeling.

II. A time extension is requested for submitting an inhalation study for each product involved. Also wanted is a decision on interpretation of existing Agency inhalation testing methodology.

The products involved are as follows: EPA 2724-337, EPA 2724-338, EPA 2724-352, EPA 2724-393, EPA 2724-427, EPA 2724-446, EPA 2724-420.

PRS Response: We recommend that a time extension of 8 months be granted minus the time of the registrant's response to the RED DCI.

A meeting involving personnel from the Registration and Health Effects Divisions decided on an interim regulatory position for inhalation testing until the FIFRA Guidelines are revised. Guidance for conducting an acute inhalation toxicity study requires the end-points of 5 mg/L concentration (for a limit test) with particle sizes of 1  $\mu\text{m}$  mass median aerodynamic diameter (MMAD) or 25% of particles  $\leq 1 \mu\text{m}$ . For some end-use pesticide products, both of these end-points cannot be met in the same study, and prove to be mutually exclusive. Insistence on the above particle size requirements has been relaxed. Particles with a MMAD  $\leq 4 \mu\text{m}$  are considered appropriate for acute inhalation toxicity testing of rats. It is felt with the larger particle sizes allowed that most end-use products will be able to fulfill both particle size and concentration end-points and result in an acceptable acute inhalation toxicity study. Upon demonstration that both end-points cannot be attained, emphasis in testing should be placed on attaining the limit concentration using the smallest particle size which will allow attainment of the limit concentration. If the particle sizes at this point are still too large to be respirable, the study will be considered an inhalation hazard test rather than an acute inhalation toxicity test. Demonstration that both end-points cannot be attained may be accomplished without exposure of animals, but efforts to reduce particle size and attain concentrations must be described in detail and submitted along with the results of the hazard test.

III. Two of the sixteen products involved are technicals (EPA 2724-441, EPA 2724-442).

PRS Response: The Agency does not need any additional acute toxicity data for methoprene technical (reference - methoprene RED).

cc: William Burnam (HED)  
Karl Baetcke (HED)  
Penelolpe Fenner-Crisp (HED)  
Marcia Van Gemert (HED)

DP BARCODE: D176372

CASE: 010616  
SUBMISSION: S414572

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 03/31/92  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 655 FORM DATA & LBL - REREG  
CHEMICALS: 105401 Methoprene (isopropyl (E,E)-11-methoxy-3,7,11-tri 4.0000%

ID#: 002724-00448 ZOECON RF-330 ALTOSID PELLETS  
COMPANY: 002724 ZOECON CORPORATION  
PRODUCT MANAGER: 18 PHILLIP HUTTON 703-305-7690 ROOM: CM2 213  
PM TEAM REVIEWER: WILLIE NELSON 703-305-6601 ROOM: CM2 209  
RECEIVED DATE: 03/02/92 DUE OUT DATE: 06/30/92

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 176372 EXPEDITE: Y DATE SENT: 03/31/92 DATE RET.: / /  
CHEMICAL: 105401 Methoprene (isopropyl (E,E)-11-methoxy-3,7,11-trimethyl-2,  
TYPE: 001 Submission Related Data Package  
ADMIN DUE DATE: 06/29/92 CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : RD	/ /	/ /
BRAN: RSB	/ /	/ /
SECT: PRS	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

TOM, PLEASE REVIEW THIS INFORMATION FOR FIFRA

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
176017	RSB/PRS	03/24/92	06/22/92	Y	Y	Y



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

2 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Methoprene Reregistration, List A - Case 0030  
Toxicology Waiver  
Product Specific ID# 2724-RD-52  
Zoecon RF-330 ALTOSID® Pellets, EPA Reg. No. 2724-448

Dear Mr. Nelson:

Zoecon Corporation requests a waiver of toxicology data for Zoecon RF-330 Altosid Pellets, EPA Reg. No. 2724-448, as presented in the Methoprene R.E.D. Case 0030. This waiver request is based on valid data previously reviewed by the Agency.

The Zoecon RF-330 Altosid Pellet, as the name implies, is a solid. It is cylindrical with a diameter of four millimeters and a length which averages ten millimeters. It looks exactly like rabbit food pellets except it's a charcoal gray color. The product is made as a mosquito control product and is not marketed through consumer channels.

The product formulation, physical characteristics, use pattern, and use history preclude the need to waste laboratory animals for a product whose safety can be determined as it would pertain to animal or human intoxication potential. Each pellet contains 4% (S)-methoprene, at least [REDACTED], greater than [REDACTED], and at least [REDACTED]. The remainder of the product is made up of [REDACTED] food grade antioxidants. All of the ingredients, except the active, are listed in 40 CFR § 180.1001(c) and elsewhere as exempted from tolerances.

The Agency has already reviewed the toxicity profile of methoprene. For all practical purposes, the remainder of this solid product is made up of [REDACTED]

[REDACTED] By exempting these ingredients from the requirement of a tolerance, obviously the Agency has reviewed the toxicity profile for each inert.

Oral ingestion of this product is of little concern. It is too large to swallow whole and chewing would be painful, as it is essentially cement. The real hazard would appear to be either choking or constipation. Since the product is solid, dermal absorption would seem remote, although the area in touch with the product may become black [REDACTED]

[REDACTED] Eye and skin irritation would be related to the already known irritative potential of methoprene (non-existent) or the physically abrasive potential of [REDACTED] when present. The inhalation safety is based on the same known patterns as described for eye and skin. The safety profile is for all practical purposes derived from physical abrasive injury due to the product rather than chemical intoxication.

Therefore, based on the above discussion, Zoecon requests a toxicology waiver on this product based on the fact that it is a solid product not readily available for human or animal misuse, the individual components of the formulation have been reviewed by the Agency, and the use history indicates an extremely safe profile both to the environment and to human/animal health. Also to determine the safety of the product in the rat and rabbit under Pesticide Assessment Guidelines, Subdivision F, the product would have to be destroyed, as sold, and pulverized into extremely fine particles to administer to the laboratory animals. It is well known that alteration of this kind alters any safety profile of the product and in no way reflects the real world safety of the product as handled and used.

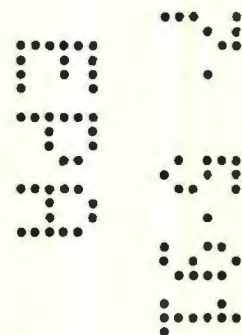
Additionally, and more importantly, the safety of the product can be determined without the sacrificing of animals. The individual components of this solid are well known toxicologically. This is a procedure and a request the Agency has made to industry via the "Revised Policy for Acute Toxicity Testing, 9/22/88, Victor J. Kimm."

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA





<b>(A)</b>  United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<b>Application for Pesticide:</b>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number <div style="font-size: 1.5em; color: red; text-align: center;">156419</div>

**Section I**

1. Company/Product Number 2724-448	2. EPA Product Manager Phil Hutton	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zoecon RF-330 ALTOSID® PELLETS	PM# 18	
5. Name and Address of Applicant (Include ZIP Code) Zoecon Corporation A Sandoz Company 12200 Denton Drive Dallas, TX 75234 <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____  Product Name _____

**Section II**

<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - explain below.
--	--

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Application for Reregistration

**Section III**

<b>1. Material This Product Will Be Packaged In:</b>				<b>2. Type of Container</b>	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* <b>Certification must be submitted.</b>		If "Yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 25 - 100 lbs.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other (_____)					

**Section IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kelly J. Parker	Title Regulatory Specialist	Telephone No. (Include Area Code) 214/888-8726
<b>Certification</b>		
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		
2. Signature 	3. Title Regulatory Specialist	
4. Typed Name Kelly J. Parker	5. Date 20 November 1991	
6. Date Application Received (Stamped) <div style="font-size: 1.5em; color: red;">275</div>		



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III (Packaging and Container Information)** - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point)** - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

20 November 1991

Mr. Willie Nelson  
Product Management Team (18)  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall, Bldg. 2  
1921 Jefferson Davis Hwy.  
Arlington, VA 22202

RE: Methoprene Reregistration, List A - Case 0030

Dear Mr. Nelson:

Enclosed in quadruplicate are data in support of reregistration of the subject products containing methoprene as the active ingredient. Please disregard suffixes in the code names for products. Those are strictly internal designations.

**Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286  
Product Specific ID# 2724-RD-7**

<u>MRID Number</u>	<u>Study</u>
_____	Wilkins, C. <u>Storage Stability of Methoprene EC 65% (RF 174) EPA Reg. No. 2724-286, 2724-405, 55947-88, 55947-94.</u> Zoecon Study Number 1747. Unpublished. 22 pages.
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 337, "Determination of Methoprene in RF 174 by Gas Chromatography Analysis".</u> Zoecon Study Number 1539. Unpublished. 16 pages.
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, pH, Flashpoint, and Viscosity of RF 174, EPA Registration Numbers 2724-286, 2724-405, 55947-88 and 55947-94.</u> Zoecon Study Number 1758. Unpublished. 23 pages.
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R174 SAN 800 I 66EC: Acute Oral Toxicity Study in Male and Female Rats . SRI Study No. LSC 2673-M027-91.</u> Zoecon Study No. 1728. Unpublished. 41 pages.
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R174 SAN 800 I 66EC: Primary Skin Irritation Study in Rabbits. SRI Study No. LSC 2673-M027-91.</u> Zoecon Study No. 1730. Unpublished. 40 pages.

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Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Eye Irritation Study in Rabbits. SRI Study No. LSC 2673-M030-91. Zoecon Study No. 1731. Unpublished. 42 pages.

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Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Acute Dermal Toxicity Study in Male and Female Rabbits . SRI Study No. LSC 2673-M028-91. Zoecon Study No. 1729. Unpublished. 39 pages.

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Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Skin Sensitization Study in Guinea Pigs . SRI Study No. LSC 2673-M031-91. Zoecon Study No. 1732. Unpublished. 60 pages.

Please note that these data are also being submitted in support of Diacon, EPA Reg. No. 55947-94, Product ID# 55947-RD-94 for our sister company, Sandoz Crop Protection Corporation.

**Apex 5E, EPA Reg. No. 55947-88  
Product Specific ID# 55947-RD-88**

Zoecon Studies 1539, 1728, 1729, 1730, 1731, 1732, 1747, 1758 are all applicable to this product. The formulations are identical, the registered use sites are different. A letter certifying Zoecon Corporation as an agent of Sandoz Crop Protection Corporation, is being provided under separate cover. As their agent, we are providing the above data in support of the Apex 5E registration currently being transferred to Zoecon.

**Zoecon RF-274 Fogger, EPA Reg. No. 2724-337  
Product Specific ID# 2724-RD-22**

MRID Number                      Study

\_\_\_\_\_  
Wilkins, C. Stability of (S)-Methoprene/Permethrin Solvent Based Fogger/Aerosol (RF274B) EPA Reg. No. 2724-337. Zoecon Study Number 1301. Unpublished. 14 pages.

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Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 63C, "Procedure for the Analysis of Permethrin and Methoprene in RF 274 and RF 280 (Solvent Based Foggers and Aerosols)". Zoecon Study Number 1539. Unpublished. 21 pages.

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Clark, A. Physical and Chemical Properties Testing for Zoecon RF-274 Fogger. MRI No. 9914-F. Zoecon No. 1672. Unpublished. 13 pages.

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McDaniel, J. Flash Point Determination of Zoecon RF-274 Fogger Concentrate. Zoecon Study Number 1680. Unpublished. 8 pages.

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Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R274B SAN 1139 I5.8AE Skin Sensitization Study in Guinea Pigs . SRI Study No. LSC 2673-M037-91. Zoecon Study No. 1738. Unpublished. 55 pages.

**Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338  
Product Specific ID# 2724-RD-23**

MRID Number                      Study

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Clark, A. Physical and Chemical Properties Testing for Zoecon RF-275 Pressurized Spray. MRI No. 9914-F. Zoecon No. 1674. Unpublished. 15 pages.

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McDaniel, J. Flash Point Determination of Zoecon RF-275 Aerosol Concentrate. Zoecon Study Number 1680. Unpublished. 8 pages.

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Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 324 "Procedure for the Analysis of Methoprene, Synergist MGK-264, Pyrethrins and PBO in a Water-Based System (Including RF 275)". Zoecon Study Number 1539. Unpublished. 19 pages.



**Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339**  
**Product Specific ID# 2724-RD-24**

<u>MRID Number</u>	<u>Study</u>
_____	Clark, A. <u>Physical and Chemical Properties Testing for Zoecon RF-280 Aerosol</u> . MRI No. 9914-F. Zoecon No. 1671. Unpublished. 13 pages.
_____	McDaniel, J. <u>Flash Point Determination of Zoecon RF-280 Aerosol Concentrate</u> . Zoecon Study Number 1680. Unpublished. 8 pages.

Zoecon Study 1301, 1539, and 1738 listed above for Zoecon RF-274 Fogger are also applicable to this product. The only difference in the two products is a small difference in the amount of propellant.

**Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352**  
**Product Specific ID# 2724-RD-25**

<u>MRID Number</u>	<u>Study</u>
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 329, "Procedure for the Analysis for Methoprene in a Methoprene Emulsifiable Concentrate (RF 291)"</u> . Zoecon Study Number 1539. Unpublished. 16 pages.
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-291, EPA Registration Number 2724-352</u> . Zoecon Study Number 1667. Unpublished. 23 pages.

**Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356**  
**Product Specific ID# 2724-RD-26**

_____	Wilkins, C. <u>Storage Stability of Methoprene Bolus (RF 293) EPA Reg. No. 2724-356</u> . Zoecon Study Number 1744. Unpublished. 19 pages.
_____	Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, and Density of RF 293, EPA Registration Number 2724-356</u> . Zoecon Study Number 1712. Unpublished. 17 pages.
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 223C, "Procedure for the Analysis of Methoprene in RF 293, (Methoprene Bolus)"</u> . Zoecon Study Number 1539. Unpublished. 16 pages.

**Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360**  
**Product Specific ID# 2724-RD-27**

<u>MRID Number</u>	<u>Study</u>
_____	Wilkins, C. <u>Storage Stability of (S)-Methoprene/Permethrin Water Based Aerosol (RF297A) EPA Reg. No. 2724-360</u> . Zoecon Number 1308. Unpublished. 14 pages.
_____	Clark, A. <u>Physical and Chemical Properties Testing for Zoecon RF-297 Aerosol</u> . MRI No. 9914-F. Zoecon No. 1673. Unpublished. 15 pages.
_____	McDaniel, J. <u>Flash Point Determination of Zoecon RF-297 Aerosol Concentrate</u> . Zoecon Study Number 1680. Unpublished. 9 pages.
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 310 "Procedure for the Analysis of Water Based Aerosols Containing Permethrin and Methoprene (including RF 297)"</u> . Zoecon Study Number 1539. Unpublished. 20 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Acute Oral Toxicity Study in Male and Female Rats. SRI Study No. LSC 2561-M008-91. Zoecon Study No. 1675. Unpublished. 34 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Acute Dermal Toxicity Study in Male and Female Rabbits. SRI Study No. LSC 2561-M009-91. Zoecon Study No. 1676. Unpublished. 43 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Primary Skin Irritation Study in Rabbits. SRI Study No. LSC 2561-M010-91. Zoecon Study No. 1677. Unpublished. 42 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Primary Eye Irritation Study in Rabbits. SRI Study No. LSC 2561-M011-91. Zoecon Study No. 1678. Unpublished. 44 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Skin Sensitization Study in Guinea Pigs. SRI Study No. LSC 2561-M012-91. Zoecon Study No. 1679. Unpublished. 59 pages.

**ALTOSID CP-10, EPA Reg. No. 2724-367**  
**Product Specific ID# 2724-RD-28**

Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density of RF 74, EPA Registration Number 2724-367. Zoecon Study Number 1712. Unpublished. 17 pages.

Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 77A, "Procedure for the Analysis of (R,S)-Methoprene in RF 74, (CP10)". Zoecon Study Number 1539. Unpublished. 16 pages.

**Granular IGR Cattle Supplement, EPA Reg. No. 2724-372**  
**Product Specific ID# 2724-RD-30**

Sheehan, T. Precision and Accuracy for Current Analytical Procedure (CAP) Number 335, "Procedure for the Analysis for (R,S)-Methoprene in Zoecon's Granular and Block Cattle Supplements EPA REG NOS 2724-372 and 2724-373". Zoecon Study Number 1721. Unpublished. 22 pages.

Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density for 9118SAN800I0.02GB, Granular Feed Supplement, EPA Registration Number 2724-372. Zoecon Study Number 1726. Unpublished. 17 pages.

**Block IGR Cattle Supplement, EPA Reg. No. 2724-373**  
**Product Specific ID# 2724-RD-31**

MRID Number      Study

Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density for 9119SAN800I0.02BB, Block Feed Supplement, EPA Registration Number 2724-373. Zoecon Study Number 1726. Unpublished. 17 pages.

Zoecon Study 1721 listed above for Granular IGR Cattle Supplement (EPA Reg. No. 2724-372) also provides precision and accuracy data for this cattle supplement product. The formulas are essentially identical.



**ALTOSID Briquets, EPA Reg. No. 2724-375**  
**Product ID# 2724-RD-33**

<u>MRID Number</u>	<u>Study</u>
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_____	Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, and Density of RF 433N, EPA Registration Number 2724-375.</u> Zoecon Study Number 1712. Unpublished. 17 pages.
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_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 325, "Procedure for the Analysis of Methoprene in RF 433N (30 Day Briquet and Briquet Premix)".</u> Zoecon Study Number 1539. Unpublished. 16 pages.
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**Kabat Tobacco Protector, EPA Reg. No. 2724-377**  
**Product Specific ID# 2724-RD-34**

<u>MRID Number</u>	<u>Study</u>
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_____	McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-385N, EPA Registration Number 2724-377.</u> Zoecon Study Number 1667. Unpublished. 23 pages.
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_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 321 "Determination of Methoprene in RF 385N and RF 386N (Kabat)".</u> Zoecon Study Number 1539. Unpublished. 17 pages.
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**Kabat Protector Concentrate, EPA Reg. No. 2724-384**  
**Product Specific ID# 2724-RD-36**

<u>MRID Number</u>	<u>Study</u>
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_____	McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-386N, EPA Registration Number 2724-384.</u> Zoecon Study Number 1667. Unpublished. 21 pages.
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Zoecon Study 1539 listed above for Kabat Tobacco Protector provides precision and accuracy data on the analytical method for both products. These two products are identical except in the level of methoprene; the Kabat Tobacco Protector is 5% methoprene and the Concentrate product is 80% methoprene.

**Altosid Liquid Larvicide, EPA Reg. No. 2724-392**  
**Product Specific ID# 2724-41**

<u>MRID Number</u>	<u>Study</u>
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_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-438N, EPA Registration Number 2724-392.</u> Zoecon Study Number 1667. Unpublished. 24 pages.
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_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 328, "Procedure for the Analysis of (S)-Methoprene in RF 437N, RF438N and RF 329 (Altosid Liquid Larvicide SR-20, SR-5 and Pharorid)".</u> Zoecon Study Number 1539. Unpublished. 23 pages.
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**Altosid Liquid Larvicide Concentrate, EPA Reg. No. 2724-393**  
**Product Specific ID# 2724-42**

<u>MRID Number</u>	<u>Study</u>
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-437N, EPA Registration Numbers 2724-393 and 2724-446.</u> Zoecon Study Number 1667. Unpublished. 24 pages.
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Acute Oral Toxicity Study in Male and Female Rats . SRI Study No. LSC 2673-M032-91.</u> Zoecon Study No. 1733. Unpublished. 36 pages.
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Acute Dermal Toxicity Study in Male and Female Rabbits . SRI Study No. LSC 2673-M033-91.</u> Zoecon Study No. 1734. Unpublished. 41 pages.
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Primary Skin Irritation Study in Rabbits . SRI Study No. LSC 2673-M034-91.</u> Zoecon Study No. 1735. Unpublished. 39 pages.
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Eye Irritation Study in Rabbits . SRI Study No. LSC 2673-M035-91.</u> Zoecon Study No. 1736. Unpublished. 44 pages.
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Skin Sensitization Study in Guinea Pigs . SRI Study No. LSC 2673-M036-91.</u> Zoecon Study No. 1737. Unpublished. 54 pages.

Zoecon Study Number 1539 listed above for Altosid Liquid Larvicide provides precision and accuracy data on the analytical method for both products.

**Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401**  
**Product Specific ID# 2724-44**

<u>MRID Number</u>	<u>Study</u>
_____	Wilkins, C. <u>Stability of (S)-Methoprene/Permethrin Pump Spray EPA Reg. No. 2724-401.</u> Zoecon Study Number 1283. Unpublished. XX pages.
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-299, EPA Registration Number 2724-401.</u> Zoecon Study Number 1667. Unpublished. 23 pages.
_____	Lephart, J. <u>Method Validation for the Analysis of (R,S)-Methoprene or (S)-Methoprene and Permethrin in a RTU Water-based Carpet Spray.</u> Zoecon Project Code R299SAN1129I.26AL. 1303 Report-VMOA. Unpublished. 62 pages.

**Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404**  
**Product Specific ID# 2724-RD-46**

<u>MRID Number</u>	<u>Study</u>
_____	Wilkins, C. <u>Stability of Ovitrol Flea &amp; Tick Pump Spray (RF322) EPA Reg. No. 2724, 401 (sic).</u> Zoecon Study Number 1283. Unpublished. XX pages.
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 242B, "Procedure for the Analysis of S-Methoprene, PBO, Pyrethrins and MGK-264 in Alcohol-Based Pump Spray (Including RF 322)".</u> Zoecon Study Number 1539. Unpublished. 20 pages.



McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-322, EPA Registration Number 2724-404. Zoecon Study Number 1667. Unpublished. 23 pages.

**Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420**  
**Product Specific ID# 2724-RD-48**

MRID Number

Study

McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-329, EPA Registration Number 2724-420. Zoecon Study Number 1667. Unpublished. 24 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R329 SAN 810 I4.8CB: Skin Sensitization Study in Guinea Pigs. SRI Study No. LSC 2673-M038-91. Zoecon Study No. 1739. Unpublished. 56 pages.

Zoecon Study 1539 listed above for ALTOSID Liquid Larvicide, EPA Reg. No. 2724-392 is also applicable to this product as they are essentially identical formulations.

**Zoecon RF-292 Briquet, EPA Reg. No. 2724-421**  
**Product Specific ID# 2724-RD-49**

MRID Number

Study

Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density of RF 292A, EPA Registration Number 2724-421. Zoecon Study Number 1712. Unpublished. 17 pages.

Nguyen, K. Method for the Assay of S-Methoprene in Briquets. Zoecon Study TR-1275. Unpublished. 70 pages.

**Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427**  
**Product Specific ID# 2724-RD-50**

MRID Number

Study

Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 330, "Procedure for the Analysis for Methoprene in RF 342 (Dianex)". Zoecon Study Number 1539. Unpublished. 16 pages.

McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-342, EPA Registration Number 2724-427. Zoecon Study Number 1667. Unpublished. 23 pages.

**Methoprene Technical, EPA Reg. No. 2724-441**  
**Product Specific ID# 2724-RD-56**

MRID Number

Study

McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of (R,S)-Methoprene, EPA Registration Number 2724-441. Zoecon Study Number 1669. Unpublished. 21 pages.



Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 284, "Procedure for The Analysis of Technical Methoprene (EPA Registration Numbers 2724-441 and 2724-442)". Zoecon Study Number 1539. Unpublished. 17 pages.

**(S)-Methoprene Technical, EPA Reg. No. 2724-442**  
**Product Specific ID# 2724-RD-51**

<u>MRID Number</u>	<u>Study</u>
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_____	McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of (S)-Methoprene, EPA Registration Number 2724-442. Zoecon Study Number 1669. Unpublished. 21 pages.
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Zoecon Study 1539 listed above for Methoprene Technical also provides precision and accuracy data for the current analytical procedure for S-Methoprene Technical.

**Zoecon RF-437 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446**  
**Product Specific ID# 2724-RD-439**

Zoecon Studies 1667, 1733, 1734, 1735, 1736, 1737 listed above for ALTOSID Liquid Larvicide Concentrate are also applicable to this product, since their formulations are identical. The only difference in the two products is in their labels; ALTOSID Liquid Larvicide is a manufacturing-use product and RF-437 carries an end-use label.

Zoecon Study 1539 listed above for ALTOSID Liquid Larvicide, EPA Reg. No. 2724-392 is also applicable to this product as they are essentially identical formulations.

**Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448**  
**Product Specific ID# 2724-RD-52**

<u>MRID Number</u>	<u>Study</u>
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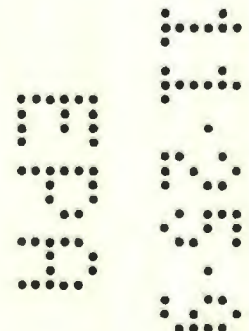
_____	Nguyen, K. Method Validation for the Analysis of (S)-Methoprene in Altosid Pellets and Premix. Zoecon Project Code R330SAN810I4XX. 1413 Report-VMOA. Unpublished. 34 pages.
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_____	Schweitzer, M. Product Chemistry of Altosid Pellets. Battelle Study Number SC900157. Zoecon Study Number 1565. Unpublished. 24 pages.
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Best regards,

*Kelly J. Parker*

Kelly J. Parker  
Regulatory Specialist  
800/527-0512



# ZOECON RF-330 ALTOSID PELLETS

MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

**ACTIVE INGREDIENT:**

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoate].....

4.0%

**INERT INGREDIENTS:**.....

96.0%

**TOTAL**..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**NET WEIGHT:** 25 lb. (11.34 kg)

643

16.93.11

## PRECAUTIONARY STATEMENTS

**ENVIRONMENTAL HAZARDS:** Do not apply to known fish habitat.

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including Culex and Culiseta spp., as well as adults of the floodwater mosquitoes such as Aedes, Anopheles and Psorophora spp. from treated sites.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID insect growth regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

HABITAT	RATES (Lbs/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste treatment settling ponds	5 - 10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-448  
1091-8:0132A;RED

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# ZOECON RF-330 ALTOSID PELLETS

MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

**ACTIVE INGREDIENT:**

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoate].....

4.0%

**INERT INGREDIENTS:**.....

96.0%

**TOTAL**..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**NET WEIGHT:** 25 lb. (11.34 kg)

643

16.93.11

## PRECAUTIONARY STATEMENTS

**ENVIRONMENTAL HAZARDS:** Do not apply to known fish habitat.

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including Culex and Culiseta spp., as well as adults of the floodwater mosquitoes such as Aedes, Anopheles and Pseorophora spp. from treated sites.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID insect growth regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

HABITAT	RATES (Lbs/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste treatment settling ponds	5 - 10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

**STORAGE AND DISPOSAL:** Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND CONDITIONS OF SALE:** Seller makes no warranty, express or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

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EPA Reg. No. 2724-448  
1091-B:0132A:RED

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# ZOECON RF-330 ALTOSID PELLETS

## MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

### ACTIVE INGREDIENT:

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-

dodecadienoate]..... 4.0%  
INERT INGREDIENTS:..... 96.0%  
TOTAL..... 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WEIGHT: 25 lb. (11.34 kg)

443

16.52.11

## PRECAUTIONARY STATEMENTS

**ENVIRONMENTAL HAZARDS:** Do not apply to known fish habitat.

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including Culex and Culiseta spp., as well as adults of the floodwater mosquitoes such as Aedes, Anopheles and Psorophora spp. from treated sites.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID insect growth regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

### APPLICATION SITES AND RATES:

HABITAT	RATES (Lbs/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste treatment settling ponds	5 - 10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

**APPLICATION METHODS:** Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

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# ZOECON RF-330 ALTOSID PELLETS

MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

## ACTIVE INGREDIENT:

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoate].....

4.0%

## INERT INGREDIENTS:

96.0%

TOTAL..... 100.0%

KEEP OUT OF REACH OF CHILDREN

## CAUTION

NET WEIGHT: 25 lb. (11.34 kg)

043

169311

## PRECAUTIONARY STATEMENTS

**ENVIRONMENTAL HAZARDS:** Do not apply to known fish habitat.

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including *Culex* and *Culiseta* spp., as well as adults of the floodwater mosquitoes such as *Aedes*, *Anopheles* and *Psorophora* spp. from treated sites.

**GENERAL DIRECTIONS:** ALTOSID Pellets release effective levels of ALTOSID insect growth regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

**NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

HABITAT	RATES (Lbs/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5
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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

DEC 6 1991

ZOECON INDUSTRIES, INC.  
12200 DENTON DRIVE  
DALLAS, TX 75234

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 11/25/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

421079-00

20 November 1991

Mr. Willie Nelson  
Product Management Team (18)  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall, Bldg. 2  
1921 Jefferson Davis Hwy.  
Arlington, VA 22202

RE: Methoprene Reregistration, List A - Case 0030

Dear Mr. Nelson:

Enclosed in quadruplicate are data in support of reregistration of the subject products containing methoprene as the active ingredient. Please disregard suffixes in the code names for products. Those are strictly internal designations.

**Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286**  
**Product Specific ID# 2724-RD-7**

<u>MRID Number</u>	<u>Study</u>
_____	Wilkins, C. <u>Storage Stability of Methoprene EC 65% (RF 174) EPA Reg. No. 2724-286, 2724-405, 55947-88, 55947-94. Zoecon Study Number 1747. Unpublished. 22 pages.</u>
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 337, "Determination of Methoprene in RF 174 by Gas Chromatography Analysis". Zoecon Study Number 1539. Unpublished. 16 pages.</u>
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J., <u>Color, Physical State, Odor, Specific Gravity, pH, Flashpoint, and Viscosity of RF 174, EPA Registration Numbers 2724-286, 2724-405, 55947-88 and 55947-94. Zoecon Study Number 1758. Unpublished. 23 pages.</u>
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R174 SAN 800 I 66EC: Acute Oral Toxicity Study in Male and Female Rats. SRI Study No. LSC 2673-M027-91. Zoecon Study No. 1728. Unpublished. 41 pages.</u>
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R174 SAN 800 I 66EC: Primary Skin Irritation Study in Rabbits. SRI Study No. LSC 2673-M029-91. Zoecon Study No. 1730. Unpublished. 40 pages.</u>

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Eye Irritation Study in Rabbits. SRI Study No. LSC 2673-M030-91. Zoecon Study No. 1731. Unpublished. 42 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Acute Dermal Toxicity Study in Male and Female Rabbits . SRI Study No. LSC 2673-M028-91. Zoecon Study No. 1729. Unpublished. 39 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Skin Sensitization Study in Guinea Pigs . SRI Study No. LSC 2673-M031-91. Zoecon Study No. 1732. Unpublished. 60 pages.

Please note that these data are also being submitted in support of Diacon, EPA Reg. No. 55947-94, Product ID# 55947-RD-94 for our sister company, Sandoz Crop Protection Corporation.

**Apex 5E, EPA Reg. No. 55947-88  
Product Specific ID# 55947-RD-88**

Zoecon Studies 1539, 1728, 1729, 1730, 1731, 1732, 1747, 1758 are all applicable to this product. The formulations are identical, the registered use sites are different. A letter certifying Zoecon Corporation as an agent of Sandoz Crop Protection Corporation, is being provided under separate cover. As their agent, we are providing the above data in support of the Apex 5E registration currently being transferred to Zoecon.

**Zoecon RF-274 Fogger, EPA Reg. No. 2724-337  
Product Specific ID# 2724-RD-22**

<u>MRID Number</u>	<u>Study</u>
	Wilkins, C. <u>Stability of (S)-Methoprene/Permethrin Solvent Based Fogger/Aerosol (RF274B) EPA Reg. No. 2724-337.</u> Zoecon Study Number 1301. Unpublished. 14 pages.
	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 63C, "Procedure for the Analysis of Permethrin and Methoprene in RF 274 and RF 280 (Solvent Based Foggers and Aerosols)".</u> Zoecon Study Number 1539. Unpublished. 21 pages.
	Clark, A. <u>Physical and Chemical Properties Testing for Zoecon RF-274 Fogger.</u> MRI No. 9914-F. Zoecon No. 1672. Unpublished. 13 pages.
	McDaniel, J. <u>Flash Point Determination of Zoecon RF-274 Fogger Concentrate.</u> Zoecon Study Number 1680. Unpublished. 8 pages.
	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R274B SAN 1139 I5.8AE Skin Sensitization Study in Guinea Pigs .</u> SRI Study No. LSC 2673-M037-91. Zoecon Study No. 1738. Unpublished. 55 pages.

**Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338  
Product Specific ID# 2724-RD-23**

<u>MRID Number</u>	<u>Study</u>
	Clark, A. <u>Physical and Chemical Properties Testing for Zoecon RF-275 Pressurized Spray.</u> MRI No. 9914-F. Zoecon No. 1674. Unpublished. 15 pages.
	McDaniel, J. <u>Flash Point Determination of Zoecon RF-275 Aerosol Concentrate.</u> Zoecon Study Number 1680. Unpublished. 8 pages.
	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 324 "Procedure for the Analysis of Methoprene, Synergist MGK-264, Pyrethrins and PBO in a Water-Based System (Including RF 275)".</u> Zoecon Study Number 1539. Unpublished. 19 pages.



**Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339**  
**Product Specific ID# 2724-RD-24**

<u>MRID Number</u>	<u>Study</u>
_____	Clark, A. <u>Physical and Chemical Properties Testing for Zoecon RF-280 Aerosol</u> . MRI No. 9914-F. Zoecon No. 1671. Unpublished. 13 pages.
_____	McDaniel, J. <u>Flash Point Determination of Zoecon RF-280 Aerosol Concentrate</u> . Zoecon Study Number 1680. Unpublished. 8 pages.

Zoecon Study 1301, 1539, and 1738 listed above for Zoecon RF-274 Fogger are also applicable to this product. The only difference in the two products is a small difference in the amount of propellant.

**Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352**  
**Product Specific ID# 2724-RD-25**

<u>MRID Number</u>	<u>Study</u>
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 329, "Procedure for the Analysis for Methoprene in a Methoprene Emulsifiable Concentrate (RF 291)"</u> . Zoecon Study Number 1539. Unpublished. 16 pages.
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-291, EPA Registration Number 2724-352</u> . Zoecon Study Number 1667. Unpublished. 23 pages.

**Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356**  
**Product Specific ID# 2724-RD-26**

_____	Wilkins, C. <u>Storage Stability of Methoprene Bolus (RF 293) EPA Reg. No. 2724-356</u> . Zoecon Study Number 1744. Unpublished. 19 pages.
_____	Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, and Density of RF 293, EPA Registration Number 2724-356</u> . Zoecon Study Number 1712. Unpublished. 17 pages.
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 223C, "Procedure for the Analysis of Methoprene in RF 293, (Methoprene Bolus)"</u> . Zoecon Study Number 1539. Unpublished. 16 pages.

**Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360**  
**Product Specific ID# 2724-RD-27**

<u>MRID Number</u>	<u>Study</u>
_____	Wilkins, C. <u>Storage Stability of (S)-Methoprene/Permethrin Water Based Aerosol (RF297A) EPA Reg. No. 2724-360</u> . Zoecon Number 1308. Unpublished. 14 pages.
_____	Clark, A. <u>Physical and Chemical Properties Testing for Zoecon RF-297 Aerosol</u> . MRI No. 9914-F. Zoecon No. 1673. Unpublished. 15 pages.
_____	McDaniel, J. <u>Flash Point Determination of Zoecon RF-297 Aerosol Concentrate</u> . Zoecon Study Number 1680. Unpublished. 9 pages.
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 310 "Procedure for the Analysis of Water Based Aerosols Containing Permethrin and Methoprene (Including RF 297)"</u> . Zoecon Study Number 1539. Unpublished. 20 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Acute Oral Toxicity Study in Male and Female Rats. SRI Study No. LSC 2561-M008-91. Zoecon Study No. 1675. Unpublished. 34 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Acute Dermal Toxicity Study in Male and Female Rabbits. SRI Study No. LSC 2561-M009-91. Zoecon Study No. 1676. Unpublished. 43 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Primary Skin Irritation Study in Rabbits. SRI Study No. LSC 2561-M010-91. Zoecon Study No. 1677. Unpublished. 42 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Primary Eye Irritation Study in Rabbits. SRI Study No. LSC 2561-M011-91. Zoecon Study No. 1678. Unpublished. 44 pages.

Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Skin Sensitization Study in Guinea Pigs. SRI Study No. LSC 2561-M012-91. Zoecon Study No. 1679. Unpublished. 59 pages.

**ALTOSID CP-10, EPA Reg. No. 2724-367**

**Product Specific ID# 2724-RD-28**

Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density of RF 74, EPA Registration Number 2724-367. Zoecon Study Number 1712. Unpublished. 17 pages.

Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 77A, "Procedure for the Analysis of (R,S)-Methoprene in RF 74, (CP10)". Zoecon Study Number 1539. Unpublished. 16 pages.

**Granular IGR Cattle Supplement, EPA Reg. No. 2724-372**

**Product Specific ID# 2724-RD-30**

Sheehan, T. Precision and Accuracy for Current Analytical Procedure (CAP) Number 335, "Procedure for the Analysis for (R,S)-Methoprene in Zoecon's Granular and Block Cattle Supplements EPA REG NOS 2724-372 and 2724-373". Zoecon Study Number 1721. Unpublished. 22 pages.

Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density for 9118SAN800I0.02GB, Granular Feed Supplement, EPA Registration Number 2724-372. Zoecon Study Number 1726. Unpublished. 17 pages.

**Block IGR Cattle Supplement, EPA Reg. No. 2724-373**

**Product Specific ID# 2724-RD-31**

MRID Number

Study

Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density for 9119SAN800I0.02BB, Block Feed Supplement, EPA Registration Number 2724-373. Zoecon Study Number 1726. Unpublished. 17 pages.

Zoecon Study 1721 listed above for Granular IGR Cattle Supplement (EPA Reg. No. 2724-372) also provides precision and accuracy data for this cattle supplement product. The formulas are essentially identical.



**ALTOSID Briquets, EPA Reg. No. 2724-375**  
**Product ID# 2724-RD-33**

<u>MRID Number</u>	<u>Study</u>
_____	Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, and Density of RF 433N, EPA Registration Number 2724-375.</u> Zoecon Study Number 1712. Unpublished. 17 pages.
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 325, "Procedure for the Analysis of Methoprene in RF 433N (30 Day Briquet and Briquet Premix)".</u> Zoecon Study Number 1539. Unpublished. 16 pages.

**Kabat Tobacco Protector, EPA Reg. No. 2724-377**  
**Product Specific ID# 2724-RD-34**

<u>MRID Number</u>	<u>Study</u>
_____	McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-385N, EPA Registration Number 2724-377.</u> Zoecon Study Number 1667. Unpublished. 23 pages.
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 321 "Determination of Methoprene in RF 385N and RF 386N (Kabat)".</u> Zoecon Study Number 1539. Unpublished. 17 pages.

**Kabat Protector Concentrate, EPA Reg. No. 2724-384**  
**Product Specific ID# 2724-RD-36**

<u>MRID Number</u>	<u>Study</u>
_____	McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-386N, EPA Registration Number 2724-384.</u> Zoecon Study Number 1667. Unpublished. 21 pages.

Zoecon Study 1539 listed above for Kabat Tobacco Protector provides precision and accuracy data on the analytical method for both products. These two products are identical except in the level of methoprene; the Kabat Tobacco Protector is 5% methoprene and the Concentrate product is 80% methoprene.

**Altosid Liquid Larvicide, EPA Reg. No. 2724-392**  
**Product Specific ID# 2724-41**

<u>MRID Number</u>	<u>Study</u>
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-438N, EPA Registration Number 2724-392.</u> Zoecon Study Number 1667. Unpublished. 24 pages.
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 328, "Procedure for the Analysis of (S)-Methoprene in RF 437N, RF438N and RF 329 (Altosid Liquid Larvicide SR-20, SR-5 and Pharorid)".</u> Zoecon Study Number 1539. Unpublished. 23 pages.

**Altosid Liquid Larvicide Concentrate, EPA Reg. No. 2724-393**  
**Product Specific ID# 2724-42**

<u>MRID Number</u>	<u>Study</u>
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-437N, EPA Registration Numbers 2724-393 and 2724-446. Zoecon Study Number 1667. Unpublished. 24 pages.</u>
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Acute Oral Toxicity Study in Male and Female Rats. SRI Study No. LSC 2673-M032-91. Zoecon Study No. 1733. Unpublished. 36 pages.</u>
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Acute Dermal Toxicity Study in Male and Female Rabbits. SRI Study No. LSC 2673-M033-91. Zoecon Study No. 1734. Unpublished. 41 pages.</u>
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Primary Skin Irritation Study in Rabbits. SRI Study No. LSC 2673-M034-91. Zoecon Study No. 1735. Unpublished. 39 pages.</u>
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Eye Irritation Study in Rabbits. SRI Study No. LSC 2673-M035-91. Zoecon Study No. 1736. Unpublished. 44 pages.</u>
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Skin Sensitization Study in Guinea Pigs. SRI Study No. LSC 2673-M036-91. Zoecon Study No. 1737. Unpublished. 54 pages.</u>

Zoecon Study Number 1539 listed above for Altosid Liquid Larvicide provides precision and accuracy data on the analytical method for both products.

**Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401**  
**Product Specific ID# 2724-44**

<u>MRID Number</u>	<u>Study</u>
_____	Wilkins, C. <u>Stability of (S)-Methoprene/Permethrin Pump Spray EPA Reg. No. 2724-401. Zoecon Study Number 1283. Unpublished. XX pages.</u>
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-299, EPA Registration Number 2724-401. Zoecon Study Number 1667. Unpublished. 23 pages.</u>
_____	Lephart, J. <u>Method Validation for the Analysis of (R,S)-Methoprene or (S)-Methoprene and Permethrin in a RTU Water-based Carpet Spray. Zoecon Project Code R299SAN11291.26AL. 1303 Report-VMOA. Unpublished. 62 pages.</u>

**Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404**  
**Product Specific ID# 2724-RD-46**

<u>MRID Number</u>	<u>Study</u>
_____	Wilkins, C. <u>Stability of Ovitrol Flea &amp; Tick Pump Spray (RF322) EPA Reg. No. 2724-401 (sic). Zoecon Study Number 1283. Unpublished. XX pages.</u>
_____	Moorman, R., Thornton, K., Nguyen, K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 242B, "Procedure for the Analysis of S-Methoprene, PBO, Pyrethrins and MGK-264 in Alcohol-Based Pump Spray (Including RF 322)". Zoecon Study Number 1539. Unpublished. 20 pages.</u>



McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-322, EPA Registration Number 2724-404. Zoecon Study Number 1667. Unpublished. 23 pages.

**Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420**  
**Product Specific ID# 2724-RD-48**

<u>MRID Number</u>	<u>Study</u>
_____	McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-329, EPA Registration Number 2724-420. Zoecon Study Number 1667. Unpublished. 24 pages.</u>
_____	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R329 SAN 810 I4.8CB: Skin Sensitization Study in Guinea Pigs. SRI Study No. LSC 2673-M038-91. Zoecon Study No. 1739. Unpublished. 56 pages.</u>

Zoecon Study 1539 listed above for ALTOSID Liquid Larvicide, EPA Reg. No. 2724-392 is also applicable to this product as they are essentially identical formulations.

**Zoecon RF-292 Briquet, EPA Reg. No. 2724-421**  
**Product Specific ID# 2724-RD-49**

<u>MRID Number</u>	<u>Study</u>
_____	Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, and Density of RF 292A, EPA Registration Number 2724-421. Zoecon Study Number 1712. Unpublished. 17 pages.</u>
_____	Nguyen, K. <u>Method for the Assay of S-Methoprene in Briquets. Zoecon Study TR-1275. Unpublished. 70 pages.</u>

**Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427**  
**Product Specific ID# 2724-RD-50**

<u>MRID Number</u>	<u>Study</u>
_____	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 330, "Procedure for the Analysis for Methoprene in RF 342 (Dianex)". Zoecon Study Number 1539. Unpublished. 16 pages.</u>
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-342, EPA Registration Number 2724-427. Zoecon Study Number 1667. Unpublished. 23 pages.</u>

**Methoprene Technical, EPA Reg. No. 2724-441**  
**Product Specific ID# 2724-RD-56**

<u>MRID Number</u>	<u>Study</u>
_____	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of (R,S)-Methoprene, EPA Registration Number 2724-441. Zoecon Study Number 1539. Unpublished. 21 pages.</u>

Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 284, "Procedure for The Analysis of Technical Methoprene (EPA Registration Numbers 2724-441 and 2724-442)". Zoecon Study Number 1539. Unpublished. 17 pages.

**(S)-Methoprene Technical, EPA Reg. No. 2724-442**  
**Product Specific ID# 2724-RD-51**

MRID Number

Study

McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of (S)-Methoprene, EPA Registration Number 2724-442. Zoecon Study Number 1669. Unpublished. 21 pages.

Zoecon Study 1539 listed above for Methoprene Technical also provides precision and accuracy data for the current analytical procedure for S-Methoprene Technical.

**Zoecon RF-437 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446**  
**Product Specific ID# 2724-RD-439**

Zoecon Studies 1667, 1733, 1734, 1735, 1736, 1737 listed above for ALTOSID Liquid Larvicide Concentrate are also applicable to this product, since their formulations are identical. The only difference in the two products is in their labels; ALTOSID Liquid Larvicide is a manufacturing-use product and RF-437 carries an end-use label.

Zoecon Study 1539 listed above for ALTOSID Liquid Larvicide, EPA Reg. No. 2724-392 is also applicable to this product as they are essentially identical formulations.

**Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448**  
**Product Specific ID# 2724-RD-52**

MRID Number

Study

42107901

Nguyen, K. Method Validation for the Analysis of (S)-Methoprene in Altosid Pellets and Premix. Zoecon Project Code R330SAN810I4XX. 1413 Report-VMOA. Unpublished. 34 pages.

42107902

Schweitzer, M. Product Chemistry of Altosid Pellets. Battelle Study Number SC900157. Zoecon Study Number 1565. Unpublished. 24 pages.

Best regards,

*Kelly J. Parker*

Kelly J. Parker  
Regulatory Specialist  
800/527-0512



11/20

Zoecon Corporation

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

25 November 1991

Mr. Phil Hutton  
Product Manager 18  
Insecticide-Rodenticide Branch  
Office of Pesticide Programs (H7504C)  
Document Processing Desk (6(a)(2))  
Room 266A, Crystal Mall 2  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Adverse Effects Discovered In Toxicology Data

Dear Mr. Hutton:

The following studies were submitted in accordance with the R.E.D. for Methoprene. These studies had surprising results; hence, considered by EPA to be adverse effects. Please note that we have not seen confirmation of these results from product use in the marketplace.

Schindler, J.E. and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC:  
Primary Skin Irritation Study in Rabbits. SRI Study No. LSC 2673-M029-91.  
Zoecon Study No. 1730. Unpublished. 40 Pages. (See note 1.)

Results: The 72-hour mean Irritation score was 1.0 placing this product in Tox Category IV; however, 2 rabbits showed irritation through 21 days after patch removal.

Schindler, J.E. and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC:  
Skin Sensitization Study in Guinea Pigs. SRI Study No. LSC 2673-M031-91.  
Zoecon Study No. 1732. Unpublished. 60 Pages. (See note 1.)

Results: This study showed a positive response.

Schindler, J.E. and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014 I 17AE:  
Primary Skin Irritation Study in Rabbits. SRI Study No. LSC 2561-M010-91.  
Zoecon Study No. 1677. Unpublished. 42 Pages. (See note 2.)

Results: The 72-hour mean irritation score was 3.8 placing this product in Tox Category III; however, 2 rabbits showed irritation to 21 days after patch removal.

part of transmittal

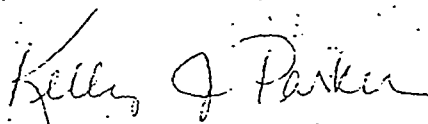
Schindler, J.E. and Baldwin, R.C. Zoecon Sample No. R437N SAN 810 I 20CS:  
Skin Sensitization Study In Guinea Pigs. SRI International. SRI Study No.  
LSC 2673-M036-91. Zoecon Study No. 1737. Unpublished. 54 Pages. (See note  
3.)

Results: This study showed a positive response.

Notes:

1. Zoecon Sample No. R174 SAN 800 I 66EC is the test material code for EPA Registration Numbers 2724-286 and 55947-88 (Under separate cover, Sandoz Crop Protection Corporation has certified Zoecon Corporation as their agent for this product pending transfer completion).
2. Zoecon Sample No. R297 ZOE 014 I .47 AE is the test material code for EPA Registration Number 2724-360.
3. Zoecon Sample No. R437N SAN 810 I 20CS is the test material code for EPA Registration Numbers 2724-393, and 2724-446.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

XC with Data: Mr. Gary Sprock  
Registration Specialist  
Department of Pesticide Regulation  
California Environmental Protection Agency  
1220 N Street  
Sacramento, CA 95814



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JAN 21 1992

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

Ms. Kelly Parker  
Regulatory Specialist  
Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive  
Dallas, TX 75234

Dear Ms. Parker:

Subject: Request for an Extension for Storage Stability Data  
To Be Submitted to the Agency and Product Chemistry  
Guideline 151B-17(1)  
(See the enclosed list of products covered)  
Your Submission Dated July 1, 1991

This letter is in response to your letter of the above date submitted in support of the subject products. Under Section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended in 1988, which requires that the Agency reregister pesticides that were first registered before November 1, 1984. Pursuant to this Act, and your response to RED issued under the Provisions of this Act, we have reviewed your submission(s)/request(s) and our conclusions are as follows:

- Your request for an extension of time to complete a 1 year storage stability study is unnecessary, since the Agency has established a policy in December 1991 to treat this data requirement much as it treats efficacy data requirements. The study is to be done and maintained in the registrants' files, but not submitted to the Agency unless the Agency specifically calls for the study at some future time.





Product Chemistry Data Requirements

The following studies are not required for the products listed in the attachment; these studies are needed only for the Technical Grade of the Active Ingredient which have been received by the Agency.

- ° Solubility
- ° Melting Point
- ° Discussion of Formation of Impurities
- ° Boiling Point
- ° Octanol/Water Partition Coefficient
- ° Stability
- ° Analysis of Samples
- ° Vapor Pressure.

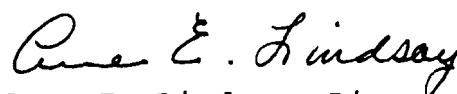
Miscibility-Data are required only if the emulsifiable liquid is intended to be diluted with petroleum solvents, but these products are not intended to be used with petroleum solvent; therefore, the data are not required.

Your request to amend your labeling to include the statement, "Breaks the flea life cycle," submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable, and a stamped copy is enclosed for your records. This stamped label does not constitute reregistration. The RED requirements are yet to be satisfied for that purpose.

Also, the Agency has no objection to the use of the Alternate Trademark "VIGREN" for your private labels instead of PRECOR which will be the trademark for your general product labelings.

Should you need further assistance, please contact Mr(s). Phil Hutton or Willie Nelson, PM Team 18, at (703) 305-6601.

Sincerely,



Anne E. Lindsay, Director  
Registration Division  
Office of Pesticide Program

STATUS OF METHOPRENE STANDARD

1. Request for a Waiver of Product Performance Data: 7/7/91

Case Number and Name: 0030 Methoprene

EPA REG. NO.'s

2724 - 375  
2724 - 392  
2724 - 393  
2724 - 446  
2724 - 448  
2724 - 421  
2724 - 286  
2724 - 337  
2724 - 338  
2724 - 339  
2724 - 352  
2724 - 356  
2724 - 360  
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2724 - 384  
2724 - 401  
2724 - 404  
2724 - 420  
2724 - 427  
2724 - 441  
2724 - 442



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Request for a Waiver of Product Performance Data  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of product performance data for the products listed below.

The requirement as listed in the Methoprene RED states that Guideline 95-10(b)(1): product performance for mosquitoes in cesspools, septic tanks, and waste treatment settling ponds should be followed. We will delete these sites from our labels, thus making the requirement not applicable to this product. Revised labels will be submitted prior to the 11/21/91 deadline.

EPA Reg. No.

Product Specific ID#

2724-375  
2724-392  
2724-393  
2724-446  
2724-448  
2724-421

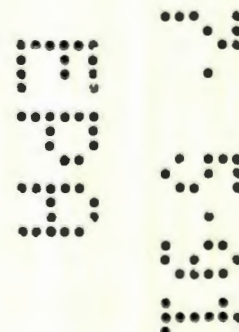
2724-RD-33  
2724-RD-41  
2724-RD-42  
2724-RD-439  
2724-RD-52  
2724-RD-49

Best regards,

*Kelly J. Parker*

Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA





# EPA

United States Environmental Protection Agency  
Washington, D.C. 20460

## REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

Form Approved

OMB No. 2070-0107

Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address <b>ZOECON CORPORATION-A SANDOZ CO. 12200 DENTON DRIVE DALLAS, TX. 75234</b>			2. Case # and Name <b>0030 Methoprene</b> Chemical # and Name <b>105401 Methoprene</b> EPA Reg. No. <b>2724-448</b>			3. Date and Type of DCI <b>PRODUCT SPECIFIC</b> ID# <b>2724-RD-52</b> <b>MAR 21 1991</b>			
4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
			1 YR	2 YRS	3 YRS				
151B-10	Product Identity					ALL	EP	8 mos.	1
151B-11	Manufacturing Process					ALL	EP	8 mos.	1
141B-12	Discussion of Impurities					ALL	EP	8 mos.	7
151B-13	Analysis of Samples					ALL	EP	8 mos.	7
151B-15	Certification of limits					ALL	EP	8 mos.	1
151B-16	Analytical method					ALL	EP	8 mos.	1
151B-17(a)	Color					ALL	EP	8 mos.	1
151B-17(b)	Physical state					ALL	EP	8 mos.	1
151B-17(c)	Odor					ALL	EP	8 mos.	1
151B-17(d)	Melting point					ALL	EP	8 mos.	7
151B-17(e)	Boiling point					ALL	EP	8 mos.	7
151B-17(f)	Density					ALL	EP	8 mos.	1
151B-17(g)	Solubility					ALL	EP	8 mos.	... 7
151B-17(h)	Vapor pressure					ALL	EP	8 mos.	... 7
151B-17(i)	pH					ALL	EP	8 mos.	... 7
151B-17(j)	Stability					ALL	EP	8 mos.	7
151B-17(k)	Flammability					ALL	EP	8 mos.	7
151B-17(l)	Storage stability					ALL	EP	8 mos.	... 7
10. Certification I certify that the statements that I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <i>Kelly J. Parker</i> Regulatory Specialist							11. Date <b>1 July 1991</b>		
12. Name of Company Contact <b>Kelly J. Parker</b>							13. Phone Number <b>214/888-8726</b>		

\*Correspondence Attached



# EPA

United States Environmental Protection Agency  
Washington, D.C. 20460

## REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

Form Approved

OMB No. 2070-0107

Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address <b>ZOECON CORPORATION-A SANDOZ CO. 12200 DENTON DRIVE DALLAS, TX. 75234</b>		2. Case # and Name <b>0030 Methoprene</b> Chemical # and Name <b>105401 Methoprene</b> EPA Reg. No. <b>2724-448</b>			3. Date and Type of DCI <b>PRODUCT SPECIFIC</b> <b>ID# 2724-RD-52</b> <b>MAR 21 1991</b>				
4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
			1 yr	2 yrs	3 yrs				
151B-17(m)	Viscosity					ALL	EP	8 mos.	7
151B-17(n)	Miscibility					ALL	EP	8 mos.	7
151B-17(o)	Corrosion characteristics					ALL	EP	8 mos.	1*
151B-17(p)	Oct/Water partition coef.					ALL	EP	8 mos.	7
152B-10	Acute oral toxicity					ALL	EP	8 mos.	7
152B-11	Acute dermal toxicity					ALL	EP	8 mos.	7
152B-12	Acute Inhal. toxicity					ALL	EP	8 mos.	7
152B-13	Primary eye irritation					ALL	EP	8 mos.	7
152B-14	Primary dermal irritation					ALL	EP	8 mos.	7
152B-15	Dermal sensitization					ALL	EP	8 mos.	7
152B-16	Hypersensitivity incidents					ALL	EP	8 mos.	1
95-10(b)(1)	Prod. Perf. for mosquitoes (cesspools, septic tanks, and waste treatment settling ponds)					Applicable sites	EP	8 mos.	7

Initial to indicate certification as to information on this page  
(full text of certification is on page one)

KP

Date

7/1/91



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

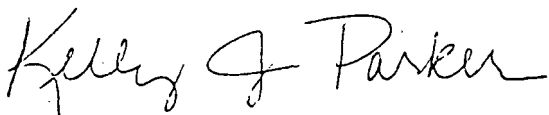
RE: Request for a Waiver of Oct/Water Partition Coefficient Data  
All End-Use Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon respectfully requests a waiver of Octanol/Water Partition Coefficient Data, Guideline Number 151B-17(p) for all end-use products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

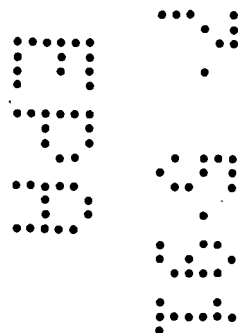
We understand that this requirement was part of the generic data requirement for the technical grade active ingredient. Data are being generated on the active ingredient and will be submitted by the April 1992 deadline. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any other product contained in the Methoprene RED.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA



## Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24

Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26

Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27

ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28

Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29

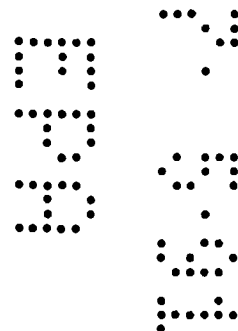
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30

Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31

ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33

Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



**Zoecon Corporation**

*A SANDOZ Company*

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Unit 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

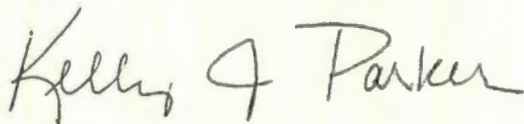
RE: Request for a Waiver of Miscibility  
All Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of miscibility, Guideline 151B-17(n), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

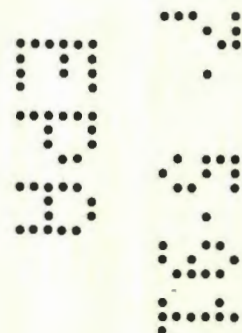
This requirement is only applicable for emulsifiable liquids intended to be diluted with petroleum solvents. Although we do have emulsifiable liquids, they are not diluted with petroleum solvents; therefore, this requirement does not apply to any product contained in the Methoprene RED.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA





## Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific

ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

Methoprene, EPA Reg. No. 2724-441 - Product Specific ID# 2724-RD-56

(S)-Methoprene Technical, EPA Reg. No. 2724-442 - Product Specific ID# 2724-RD-51

Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific

ID# 2724-RD-439

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24

Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26

Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27

ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28

Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific

ID# 2724-RD-29

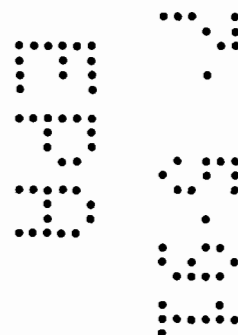
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30

Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31

ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33

Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1. July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Request for a Waiver of Viscosity Data  
All Pressurized and Solid Products Listed in the RED  
Case Number and Name: 0030 Methoprene

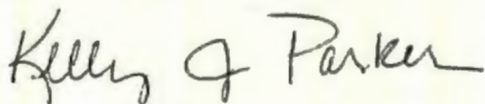
Dear Mr. Nelson:

Zoecon respectfully requests a waiver of viscosity data, Guideline Number 151B-17(m) for all pressurized and solid products subject to the Methoprene Reregistration Eligibility Decision document (see list below). Viscosity data are required only if the product is a liquid per 40 CFR § 158.190 (b)(8).

Pressurized and Solid Products

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22  
Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23  
Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24  
Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26  
Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27  
ALTOSID® CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28  
Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29  
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30  
Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31  
ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33  
Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49  
Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

20 May 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Request for an Extension of Storage Stability Data  
Guideline 151B-17(I)  
Product Specific ID# 2724-RD-52  
EPA Reg. No. 2724-448

Dear Mr. Nelson:


Zoecon Corporation respectfully requests an extension for submission of storage stability data for the subject product. We would like to submit a final report for this study in February 1992.

According to FIFRA as amended in 1988, there is no legislated timeframe for submission of product specific data for List A products (although Lists B, C, and D are subject to the 8 month rule); therefore, the length of our requested extension should pose no regulatory problem. For storage stability studies, EPA currently requires 3 lots, 3 temperatures, and 1 year's worth of GLP data. In the best of circumstances, this is unachievable within 8 months.

According to 40 CFR § 160.29(c), "There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol." Considering all of the GLP storage stability studies required by the Methoprene RED, Zoecon would need to hire 50 more people to conduct the studies, as well as the inherent need to build more stability storage space. I've been told by management that these are not viable options. We have come up with a schedule that would allow Zoecon to comply with the RED by conducting the stability studies in shifts. This will also allow Zoecon to remain in compliance with § 160.29(c) and allow us to use available storage space.

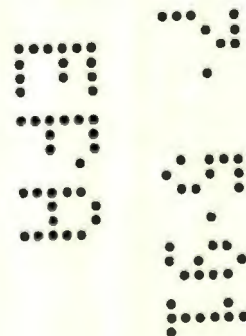
Please let me know as soon as possible whether our request for an extension has been granted.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Karen Samek, SRRD, EPA





**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Request for a Waiver of Flammability Data  
All Solid Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

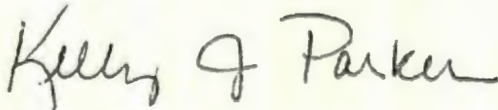
Zoecon respectfully requests a waiver of flammability data, Guideline Number 151B-17(k) for all solid products subject to the Methoprene Reregistration Eligibility Decision document (see list below).

Flammability data are required only if the product contains a combustible liquid per 40 CFR §158.190 (b)(6). These solid products do not contain combustible liquids.

Solid Products

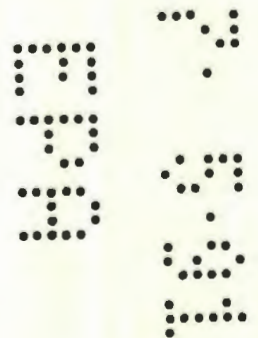
Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26  
ALTOSID® CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28  
Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29  
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30  
Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31  
ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33  
Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49  
Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202


RE: Correspondence for Storage Stability and Corrosion Characteristics  
All Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation conducts these studies together; therefore, the attached requests for extension of submitting storage stability data also apply to the corrosion characteristics portion of the study. We apologize for any inconvenience this oversight may have caused.

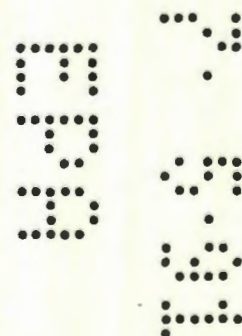
These requests are resubmitted here because we haven't received a response from EPA.

Best regards,



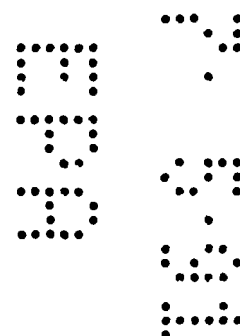
Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA



## Products

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25  
Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34  
Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36  
Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42  
Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48  
Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50  
Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific  
ID# 2724-RD-439  
Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23  
ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28  
Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific  
ID# 2724-RD-29  
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30  
Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31  
ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33  
Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49  
Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52





**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Request for a Waiver of Vapor Pressure  
All Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of vapor pressure, Guideline 151B-17(h), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

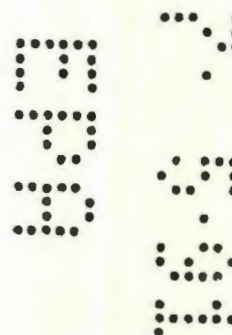
This requirement is only applicable for active ingredients. The vapor pressure for Methoprene can be found in MRID Number 00010927. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any other product contained in the Methoprene RED.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA



## Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific

ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific

ID# 2724-RD-439

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24

Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26

Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27

ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28

Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific

ID# 2724-RD-29

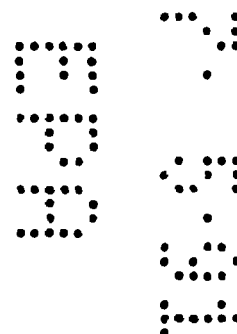
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30

Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31

ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33

Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Request for a Waiver of pH Data  
All Solid Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon respectfully requests a waiver of pH data, Guideline Number 151B-17(l) for all solid products listed in the RED (see list below). These data are required for products that are dispersible in water per 40 CFR158.190(b)(4).1 These products are not dispersible in water.

Solid Products

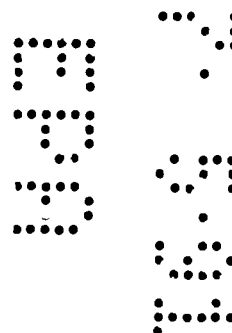
Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26  
ALTOSID® CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28  
Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29  
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30  
Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31  
ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33  
Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49  
Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52

Best regards,

*Kelly J. Parker*

Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA





**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Request for a Waiver of Stability  
All Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of stability, Guideline 151B-17(j), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

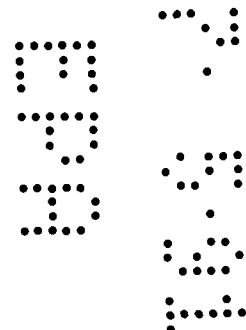
This requirement is only applicable for technical grade active ingredients. The stability of Methoprene can be found in MRID Number 00010927. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any product contained in the Methoprene RED.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA



## Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24

Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26

Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27

ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28

Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29

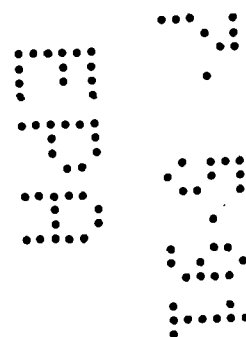
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30

Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31

ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33

Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Request for a Waiver of Solubility  
All Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of solubility, Guideline 151B-17(g), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

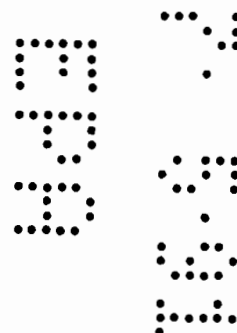
This requirement is only applicable for technical grade active ingredients. The solubility of Methoprene can be found in MRID Number 00010927. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any other product contained in the Methoprene RED.

Best regards,

*Kelly J. Parker*

Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA





## Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific

ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific

ID# 2724-RD-439

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24

Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26

Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27

ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28

Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific

ID# 2724-RD-29

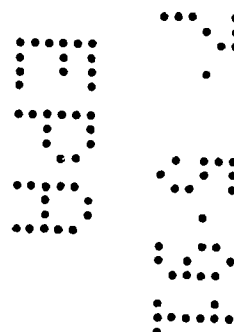
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30

Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31

ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33

Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



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1 July 1991

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Product Management Team 18  
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Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

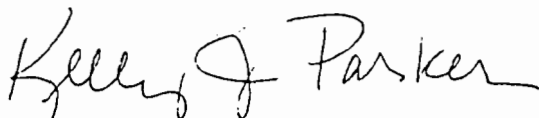
RE: Request for a Waiver of Boiling Point  
All Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of boiling point, Guideline 151B-17(e), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

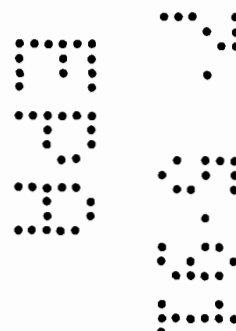
This requirement is only applicable for technical grade active ingredients that are liquid at room temperature. The boiling point for Methoprene can be found in MRID Number 00010927. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any other product contained in the Methoprene RED.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA



## Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24

Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26

Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27

ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28

Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29

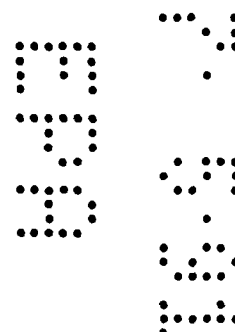
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30

Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31

ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33

Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52





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1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

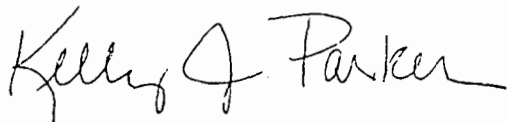
RE: Request for a Waiver of Melting Point  
All Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of melting point, Guideline 151B-17(d), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

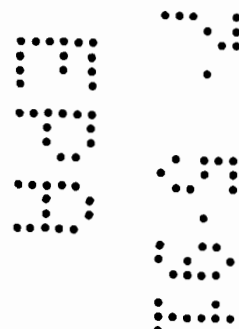
This requirement is only applicable for technical grade active ingredients that are solid at room temperature. Methoprene is a liquid at room temperature; therefore, this requirement does not apply to any product contained in the Methoprene RED.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA



## Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific

ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

Methoprene, EPA Reg. No. 2724-441 - Product Specific ID# 2724-RD-56

(S)-Methoprene Technical, EPA Reg. No. 2724-442 - Product Specific ID# 2724-RD-51

Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific

ID# 2724-RD-439

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24

Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26

Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27

ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28

Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific

ID# 2724-RD-29

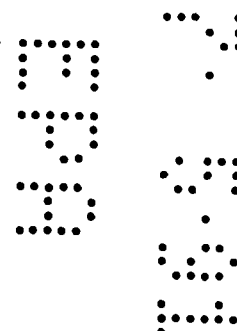
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30

Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31

ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33

Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

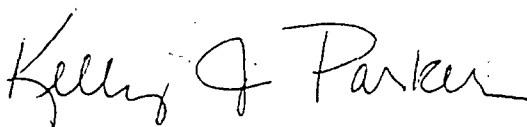
RE: Request for a Waiver of Analysis of Samples  
All End-Products and Manufacturing-Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of the analysis of samples, Guideline 151B-13, for all end-products and manufacturing-products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

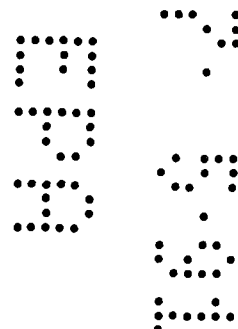
These products are not technical active ingredients and they are not produced by an integrated system; therefore, this requirement is not applicable.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA





## Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific  
ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific

ID# 2724-RD-439

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24

Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26

Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27

ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28

Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific

ID# 2724-RD-29

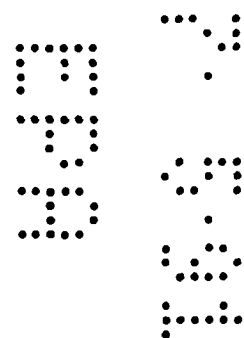
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30

Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31

ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33

Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



**Zoecon Corporation**

A SANDOZ Company

1 July 1991

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

674

RE: Request for a Waiver of Discussion of Formation of Impurities  
All End-Products and Manufacturing-Products Listed in the RED  
Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of the discussion of Impurities, Guideline 151B-12, for all end-products and manufacturing-products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

These products are not technical active ingredients and they are not produced by an integrated system. The manufacturing and use history of these products show no reactions between the product and the packaging or between ingredients in the product. We've seen no reactions occurring between the product and the production equipment. These products do not contain impurities of toxicological concern such as N-nitrosamines, hexachlorobenzene, polychlorinated or polybrominated dibenzo-p-dioxins or -furans.

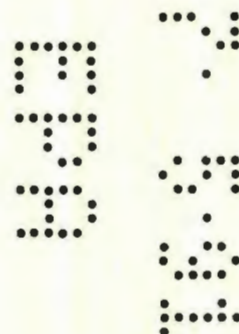
According to EPA, "end-use products are typically mixtures having no reactions occurring." This is a true statement in the case of Methoprene-containing products. The chemists' time would be better spent generating product-specific product chemistry due by November, rather than theorizing about the possibilities of impurities. Therefore, we request this waiver.

Best regards,

*Kelly J. Parker*

Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Dick King, SRRD, EPA



## Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific  
ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific  
ID# 2724-RD-439

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24

Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26

Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27

ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28

Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific  
ID# 2724-RD-29

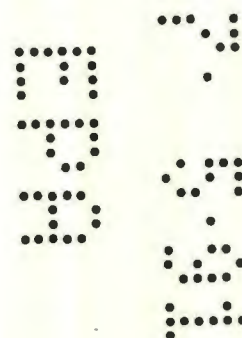
Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30

Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31

ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33

Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52





**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

20 May 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202



RE: Request for an Extension of Storage Stability Data  
Guideline 151B-17(I)  
Product Specific ID# 2724-RD-52  
EPA Reg. No. 2724-448

Dear Mr. Nelson:

Zoecon Corporation respectfully requests an extension for submission of storage stability data for the subject product. We would like to submit a final report for this study in February 1992.

According to FIFRA as amended in 1988, there is no legislated timeframe for submission of product specific data for List A products (although Lists B, C, and D are subject to the 8 month rule); therefore, the length of our requested extension should pose no regulatory problem. For storage stability studies, EPA currently requires 3 lots, 3 temperatures, and 1 year's worth of GLP data. In the best of circumstances, this is unachievable within 8 months.

According to 40 CFR § 160.29(c), "There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol." Considering all of the GLP storage stability studies required by the Methoprene RED, Zoecon would need to hire 50 more people to conduct the studies, as well as the inherent need to build more stability storage space. I've been told by management that these are not viable options. We have come up with a schedule that would allow Zoecon to comply with the RED by conducting the stability studies in shifts. This will also allow Zoecon to remain in compliance with § 160.29(c) and allow us to use available storage space.

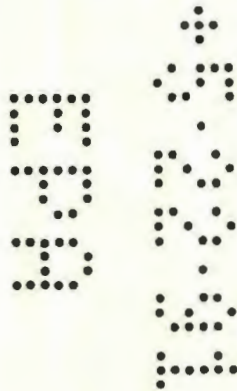
Please let me know as soon as possible whether our request for an extension has been granted.

Best regards,

A handwritten signature in cursive script that reads "Kelly J. Parker".

Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Karen Samek, SRRD, EPA



PRODUCT CHEMISTRY REVIEW

TO: PM \_\_\_\_\_ FROM: Reviewer: INDIRA GAIROLA Date: 11/18/91 <sup>Anna Skapars</sup> 11-18-91  
 EPA REG. NO.: 2724-448 PRODUCT NAME: ZOECON RF-330 ALTOSID PELLETS

FOOD USE ( ) INERTS CLEARED: C ( ), D ( ), E ( ) NON FOOD USE ( )  
 21 CFR PARTS 170-199: ( ) TOXIC INERTS LIST 1 ( ), 2 ( )

Please provide the requested information for the following checked items:

1. ☐ Submit the product specific product chemistry data for your product. ☐ If submitted earlier, provide MRID Number(s). ☐ Your product is not sufficiently similar to the product you referenced.
2. In reference to the Confidential Statement of Formula (CSF), please provide the following:
  - ☐ a) pH of product or pH at a specified water dilution.
  - ☐ b) Density of product.
  - ☐ c) Flash point of product.
  - ☐ d) Flash point of product with propellant as per item #6(q) or item #5(c).
  - ☐ e) Flame extension of product including flashbacks if noted.
  - ☐ f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.
  - ☐ g) The upper and lower certified limits of the individually added inerts.
  - ☐ h)
  - ☐ i)
  - ☐ j)

3. ☐ Based on the current CSF dated \_\_\_\_\_, your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so that the information agrees.

The applicant has requested for the waiver of certain p.c. data. The same will be discussed on the following page + justification for granting waiver.

As per extension of time for Storage Stability (1 year data) + Corrosion Characteristics may be granted or approved up to a period of 18 months. The applicant has requested an extension for submission of these data in Feb 1992.



Stability Request for waiver is granted since this is an EP & requirement is only for TGA1

Flammability is N/A since this is a solid & does not contain any combustible liquid.

PH Waiver is granted since this is N/A because it's a solid.

Miscibility Waiver is granted since this is applicable for only emulsifiable liquids, intended to be diluted with petroleum solvents.

Oct/Water Partition Co-efficient Data is not required for end use products so waiver is granted.

Vapor Pressure Waiver for V.P. is granted & is only required for the technicals.

Discussion of Formation of Impurities Waiver for this is also granted, since the same is required only of a Technical active ingredient.

Solubility Request for waiver is granted since this applies to TGA1 only.

Boiling Point Waiver is granted since this is an EP.

Melting Point Waiver is granted " " " " " "

Analysis of Samples " " " " " " an EP.

Viscosity Data are not required since this is a solid.



**Zoecon Corporation**

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

20 May 1991

Mr. Willie Nelson  
Product Management Team 18  
U.S. Environmental Protection Agency  
Document Processing Desk (RED/RD-0030)  
Office of Pesticide Programs (H7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

RE: Request for an Extension of Storage Stability Data  
Guideline 151B-17(l)  
Product Specific ID# 2724-RD-52  
EPA Reg. No. 2724-448

Dear Mr. Nelson:

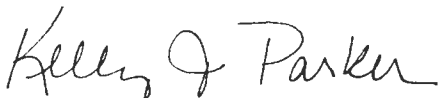
Zoecon Corporation respectfully requests an extension for submission of storage stability data for the subject product. We would like to submit a final report for this study in February 1992.

According to FIFRA as amended in 1988, there is no legislated timeframe for submission of product specific data for List A products (although Lists B, C, and D are subject to the 8 month rule); therefore, the length of our requested extension should pose no regulatory problem. For storage stability studies, EPA currently requires 3 lots, 3 temperatures, and 1 year's worth of GLP data. In the best of circumstances, this is unachievable within 8 months.

According to 40 CFR § 160.29(c), "There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol." Considering all of the GLP storage stability studies required by the Methoprene RED, Zoecon would need to hire 50 more people to conduct the studies, as well as the inherent need to build more stability storage space. I've been told by management that these are not viable options. We have come up with a schedule that would allow Zoecon to comply with the RED by conducting the stability studies in shifts. This will also allow Zoecon to remain in compliance with § 160.29(c) and allow us to use available storage space.

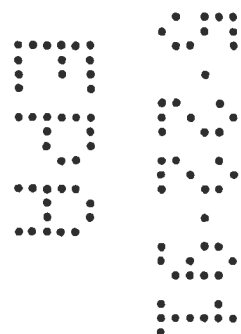
Please let me know as soon as possible whether our request for an extension has been granted.

Best regards,



Kelly J. Parker  
Regulatory Specialist  
800/527-0512

CC: Phil Hutton, RD, EPA  
Karen Samek, SRRD, EPA



161  
~~200~~ | 242232  
 17 | 25

NOV 29 1990

Ms. Kelly J. Parker  
 Regulatory Specialist  
 Zoecon Corporation  
 12200 Denton Drive  
 Dallas, TX 75234

Dear Ms. Parker:

Subject: Zoecon RF-330 ACTOSID® Pellets  
 EPA Registration No. 2724-448  
 Your Application Dated May 16, 1990

The labeling referred to above, submitted in connection with  
 registration under the Federal Insecticide, Fungicide, and Rodenticide  
 Act, as amended, is acceptable. A stamped copy is enclosed for your  
 records.

Sincerely yours,

*Phil Hutton*

Phil Hutton  
 Product Manager (17)  
 Insecticide-Rodenticide Branch  
 Registration Division (H7505C)

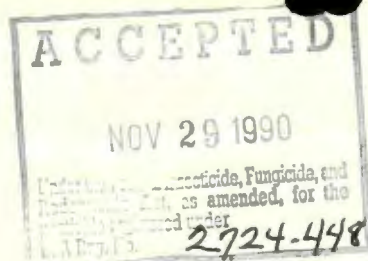
Enclosure

58031:I:A-4:Hollis:L17-20:KENCO:11/10/90:12/9/90:EK:JH:DD

CONCURRENCES

SYMBOL							
SURNAME							
DATE							





## ZOECON RF-330 ALTOSID PELLETS

MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

### ACTIVE INGREDIENT:

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-

dodecadienoate]\*..... 4.0%  
INERT INGREDIENTS:..... 96.0%  
Total.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WEIGHT : 25 lb (11.34 kg)

643

06.27.94

### PRECAUTIONARY STATEMENTS

ENVIRONMENTAL HAZARDS: Do not apply to known fish habitat.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INTRODUCTION: ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including Culex and Culiseta spp., as well as adults of the floodwater mosquitoes such as Aedes, Anopheles and Psorophora spp. from treated sites.

GENERAL DIRECTIONS: ALTOSID Pellets release effective levels of ALTOSID insect growth regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

NOTE: This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

### APPLICATION SITES AND RATES:

HABITAT	RATES (Lbs/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste treatment settling ponds	5 - 10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

APPLICATION METHODS: Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

STORAGE & DISPOSAL: Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND CONDITIONS OF SALE: Seller makes no warranty, express or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

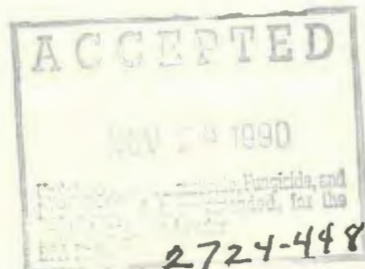
Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-448  
\*U.S. Patents 3,904,662 and 3,912,815  
0590-B:0137A

EPA Est. No.  
Made in USA  
c 1988 ZOECON

336





## ZOECON RF-330 ALTOSID PELLETS

MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

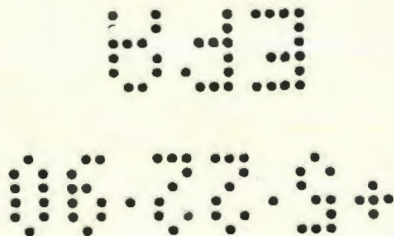
**ACTIVE INGREDIENT:**

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoate]\*..... 4.0%  
INERT INGREDIENTS:..... 96.0%  
Total.....100.0%

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

**NET WEIGHT :** 25 lb (11.34 kg)



11-29-90

### PRECAUTIONARY STATEMENTS

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### APPLICATION SITES AND RATES:

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Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
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Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-448  
\*U.S. Patents 3,904,662 and 3,912,815  
0590-B:0132A

EPA Est. No.  
Made in USA  
c 1980 ZOECON

337





United States Environmental Protection Agency  
Office of Pesticide Programs (TS-767)  
Washington, DC 20460

OPP Identifier Number

133720

Application for Pesticide: ☐ Registration ☒ Amendment

## Section I

1. Company/Product Number 2724-448	2. Date May 16, 1990	3. Product Manager Phil Hutton (17)	4. Proposed Classification <input checked="" type="checkbox"/> General <input type="checkbox"/> Restricted
---------------------------------------	-------------------------	--	---

5. Name and Address of Applicant (Include ZIP Code)

Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive  
Dallas, Texas 75234

☐ Check if this is a new address

6. Product Name

Zoecon RF-330 ALTOSID (R) PELLETS

## Section II - Amendment Information

1. Subject <input type="checkbox"/> Resubmission in response to Agency letter <input checked="" type="checkbox"/> Final printed label in response to Agency letter <input type="checkbox"/> Other (explain below)	Date of Letter April 30, 1990
--	----------------------------------

## Section III

1. Material This Product Will Be Packaged In		2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit package wgt No. per container	Water-Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package weight No. per container	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Paper Other (Specify)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 25 - 100 lbs.	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On material accompanying product		6. Manner in Which Label Is Affixed To Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other (Specify) <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

## Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).		
Name Kelly J. Parker		
Title Regulatory Specialist	Telephone No. (Include Area Code) 214-888-8726	6. Date Application Received (Stamped)
<p><b>Certification</b></p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>		
2. Signature 	3. Title Regulatory Specialist	
4. Typed Name Kelly J. Parker	5. Date Signed May 16, 1990	



# Paperwork Reduction Act Notice and Instructions

## Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

## Instructions

### General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

### Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**Section I** - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

### Amendment Information

**Section II** - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

### Packaging and Container Information

**Section III** - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

### Contact Point

**Section IV** - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.



US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">EPA REGISTRATION NO. 2724-448</td> <td style="width: 50%; padding: 2px;">DATE OF ISSUANCE APR 30 1990</td> </tr> <tr> <td colspan="2" style="padding: 2px;">TERM OF ISSUANCE</td> </tr> <tr> <td colspan="2" style="padding: 2px;">NAME OF PESTICIDE PRODUCT Zoecon RF-330 Altosid Pellets</td> </tr> </table>	EPA REGISTRATION NO. 2724-448	DATE OF ISSUANCE APR 30 1990	TERM OF ISSUANCE		NAME OF PESTICIDE PRODUCT Zoecon RF-330 Altosid Pellets	
EPA REGISTRATION NO. 2724-448	DATE OF ISSUANCE APR 30 1990						
TERM OF ISSUANCE							
NAME OF PESTICIDE PRODUCT Zoecon RF-330 Altosid Pellets							
<b>NOTICE OF PESTICIDE:</b> <input checked="" type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION (Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)							
NAME AND ADDRESS OF REGISTRANT (Include ZIP code)							
<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Zoecon Corporation            12005 Ford Road, Suite 800            Dallas, Texas 75234-7296</p> </div> <div style="width: 35%; text-align: right;"> <p>263650 / 160            18</p> </div> </div>							
<b>NOTE:</b> Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.							
On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.							
A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.							
Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.							
<p style="text-align: center;">This product is conditionally registered in accordance with FIFRA section 3(c)(7)(C) provided that you:</p> <ol style="list-style-type: none"> <li>1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.</li> <li>2. Add the phrase "EPA Registration No. 2724-448" to your label before you release the product for shipment.</li> <li>3. Add the phrase "Do not apply to known fish habitat." to the ENVIRONMENTAL HAZARDS portion of the label.</li> <li>4. Provide new product chemistry data for this product in accordance with 40 CFR 158.150 through 158.190. The product chemistry data cited in file 2724-375 for Altosid Briquets (7.9% methoprene) are not applicable to this product which contains 4.0% methoprene. When the percentages are altered, a new data base must be developed for each new mixture.</li> </ol>							
<input type="checkbox"/> ATTACHMENT IS APPLICABLE							
SIGNATURE OF APPROVING OFFICIAL <i>See P. 2</i>	DATE 4/30/90						



5. In the ingredient statement of the proposed label, change "closed parenthesis" to "closed bracket" after dodecadienoate as follows:

[Isopropyl (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]

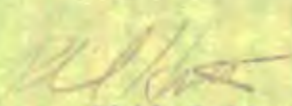
6. Provide storage stability data by product analysis for active ingredient at time zero and after a year of storage. The storage should be in warehouse conditions of temperature and humidity and stored in containers similar to those you will be using in the trade.

7. Submit five (5) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 5(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

  
Phil Hutton  
Product Manager (17)  
Insecticide/Rodenticide Branch  
Registration Division (H7505C)

Enclosure

CONCURRENCES

SYMBOL	2224-448						
SURNAME	Bagley						
DATE	4-30-90						



# ZOECON RF-330 ALTOSID PELLETS

MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

## ACTIVE INGREDIENT:

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoate)\*.....

4.0%

INERT INGREDIENTS.....

96.0%

Total 100.0%

KEEP OUT OF REACH OF CHILDREN

## CAUTION

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

APR 30 1990

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide  
registered under EPA Reg. No.

2724-448

NET WEIGHT: 25 lb (11.34 kg)

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INTRODUCTION: ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including Culex and Culiseta spp., as well as adults of the floodwater mosquitoes such as Aedes, Anopheles and Psorophora spp. from treated sites.

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NOTE: This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

HABITAT	RATES (Lbs/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
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Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-  
\*U.S. Patents 3,904,662 and 3,912,815  
688-A-0132A:0008E

EPA Est. No.  
Made in USA  
c 1988 Zoecon



15. 4150 *glaucochloris* *Meesters*

# ZOECON RF-330 ALTOSID PELLETS

MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

## ACTIVE INGREDIENT:

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoate]

INERT INGREDIENTS..... 96.0%  
Total 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WEIGHT: 25 lb (11.34 kg)

RECEIVED  
with COMMENTS  
in EPA Letter Dated:

APR 30 1990

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the Pesticide  
registered under EPA Reg. No.

2724-448

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INTRODUCTION: ALTOSID Pellets release ALTOSID insect growth regulator as they erode. ALTOSID Pellets prevent the emergence of adult standing water mosquitoes, including Culex and Culiseta spp., as well as adults of the floodwater mosquitoes such as Aedes, Anopheles and Psorophora spp. from treated sites.

GENERAL DIRECTIONS: ALTOSID Pellets release effective levels of ALTOSID insect growth regulator for up to 30 days under typical environmental conditions. Treatment should be continued through the last brood of the season. Treated larvae continue to develop normally to the pupal stage where they die.

NOTE: This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

HABITAT	RATES (Lbs/Acre)
<b>FLOODWATER SITES</b>	
Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
<b>PERMANENT WATER SITES</b>	
Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5
Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste treatment settling ponds	5 - 10

Use lower rates when water is shallow, vegetation and/or pollution are minimal and mosquito populations are low. Use higher rates when water is deep (>2 ft), vegetation and/or pollution are high and mosquito populations are high.

APPLICATION METHODS: Apply ALTOSID Pellets up to 15 days prior to flooding, or at any stage of larval development after flooding or in permanent water sites. Fixed wing aircraft or helicopters equipped with granular spreaders capable of applying rates from 2.5 - 10 lbs/acre may be used to apply ALTOSID Pellets. The Pellets may also be applied using ground equipment which will achieve good, even coverage at the above rates. ALTOSID Pellets may be applied to artificial containers such as tires and catch basins, etc.

## STORAGE & DISPOSAL:

Store closed containers of ALTOSID Pellets in a cool, dry place. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND CONDITIONS OF SALE: Seller makes no warranty, express or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-  
\*U.S. Patents 3,904,662 and 3,912,815  
688-A-0132A:0008E

EPA Est. No.  
Made in USA  
© 1988 Zoecon

# ZOECON RF-330 ALTOSID PELLETS

MOSQUITO GROWTH REGULATOR

A Granular Product to Prevent Adult Mosquito Emergence

## ACTIVE INGREDIENT:

(S)-Methoprene [Isopropyl (2E,4E,7S)-  
11-methoxy-3,7,11-trimethyl-2,4-  
dodecadienoate)\*.....

4.0%

INERT INGREDIENTS.....

96.0%

Total 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

APR 30 1990

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide  
registered under EPA Reg. No.

2724-448

NET WEIGHT: 25 lb (11.34 kg)

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NOTE: This insect growth regulator has no effect on mosquitoes which have reached the pupal or adult stage prior to treatment.

## APPLICATION SITES AND RATES:

HABITAT	RATES (Lbs/Acre)
---------	------------------

### FLOODWATER SITES

Pastures, meadows, ricefields, freshwater swamps and marshes, salt and tidal marshes, woodland pools, floodplains, tires, other artificial water holding containers	2.5 - 5
---	---------

Dredge spoil sites, waste treatment settling ponds, ditches and other man-made depressions	5 - 10
--	--------

### PERMANENT WATER SITES

Ornamental ponds and fountains, flooded crypts, transformer vaults, abandoned swimming pools, construction and other man-made depressions, treeholes, other artificial water holding containers	2.5 - 5
---	---------

Storm drains, catch basins, roadside ditches, cesspools, septic tanks, waste treatment settling ponds	5 - 10
---	--------

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WARRANTY AND CONDITIONS OF SALE: Seller makes no warranty, express or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-  
\*U.S. Patents 3,904,662 and 3,912,815  
688-A:0132A:0008E

EPA Est. No.  
Made in USA  
c 1988 Zoecon



# EXPEDITE REVIEW

DATE: 4/4/90 PRODUCT CHEMIST/REVIEWER: MICHAEL J. CLIFFORD

PAGE: 1 OF 1 CONCURRED BY: Anna Skapars 24-4-90

COMPANY: ZOECON CORPORATION EPA REG. NO: 2724-UEO

PRODUCT NAME: ZOECON RF-330 ALTOSID PELLETS

TO PM NO: 17 ACTION CODE: 160

BACKGROUND: new registration of product for use as an extended release formulation to prevent adult mosquito emergence in standing water.

ACTIVE INGREDIENT LABEL CLAIM/ LATEST LABEL CLAIM (DATED / / )

S-METHOPRENE: ISOPROPYL (2E, 4E, 7S) -  
11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIEENOATE (4.0%)

REFERENCES USED: EPA 2724-442

FOOD USE ( ) INERTS CLEARED C( ), D( ) NON FOOD USE (X)  
CFR 21 PARTS 170-199 ( ) TOXIC INERTS LIST 1( ), 2( )

COMMENTS: a. CSF dated 6/24/88 is filled out correctly, it agrees with the label and is acceptable.

b. In reference to the METHOPRENE source product, Sandoz Crop Protection Corp.'s EPA 55947-109 has been transferred to Zoecon Corp.'s EPA 2724-442.

c. In the ingredient statement of the proposed label, change "closed parenthesis" to "closed bracket" after dodecadienoate: [ISOPROPYL (2E, 4E, 7S)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIEENOATE].

d. The product chemistry data cited in Zoecon Corp.'s EPA 2724-375 for ALTOSID BRIQUETS (7.9% METHOPRENE) are not applicable to ZOECON RF-330 ALTOSID PELLETS (4.0% METHOPRENE).

When the percentages are altered, a new data base must be developed for each new mixture. Therefore, you should provide new-product chemistry data for your product in accordance with 40CFR Parts 158.150 through 158.190.

Michael J. Clifford



DATE: 1/8/90

PAGE 1 OF 1

FROM: MICHAEL CLIFFORD

TO PM NO: 17 (HUTTON)

PRODUCT NAME: ZOECON RF-330  
ALTOSID PELLETS

ACTION CODE: 160

RSB PRODUCT CHEMISTRY REVIEW

CONCURRED: T. R. Allen

EPA REG. NO.: 2724-UH4

COMPANY NAME: ZOECON CORP.

BACKGROUND: Registration of the product as a  
mosquito growth regulator.

ACTIVE INGREDIENT LABEL CLAIMS:

S-METHOPRENE: ISOPROPYL (2E, 4E, 7S)-	(4.0%)
11-METHOXY-3, 7, 11-TRIMETHYL-2, 4-	( )
DODECADienoate	( )

REFERENCES USED: Requested jackets on 1-2-90.

FOOD USE ( ) NON-FOOD USE (X) INERTS CLEARED (X)

CFR 21 PARTS 170-199 ( )

TOXIC INERT(S) OF CONCERN:

COMMENTS:

NOTE TO PM: The review of this submission  
cannot be completed due to the unavailability  
of the following registration jackets:

EPA REG. NO. 55947-109 (Sandoz Crop Protection Corp.)

EPA REG. NO. 2724-375 (Zoecon Corp.)

EPA REG. NO. 2724-389 (Zoecon Corp.)

Michael J. Clifford 1/18/90

448

Record Number \_\_\_\_\_  
Reference Number \_\_\_\_\_  
Input Date \_\_\_\_\_

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 2724-001 PM 17 | 8 | Action Code \_\_\_\_\_

|10| Descriptor (Amend/Resubmissions only) \_\_\_\_\_

|5| Intrastate Call-in ☐ (Y) Yes |15| Child-resistant Packaging ☐ (C) Certification  
☐ (N) No ☐ (S) Service Person

|20| Registration Type:  
☐ (1) Conditional ☐ (2) Unconditional  
☐ (R) Non-residential Use Only  
☐ (N) Not-Applicable

|25| Proposed Classification: |30| Final Classification:

☐ (R) Restricted ☐ (R) Restricted  
☐ (G) General ☐ (N) Not Classified

|35| Date on Application: |04| EPA Received Date: |40| Date Received by PM  
016 | 217 | 88 | 016 | 217 | 88 | \_\_\_\_\_ | \_\_\_\_\_ | \_\_\_\_\_  
MO DAY YR MO DAY YR MO DAY YR

|80| Method of Support: |85| Certification Statement:  
☐ (1) Cite-All ☐ (6) Owner Submission ☐ (1) Yes  
☐ (4) Not Applicable ☐ (7) Total Submission ☐ (2) Not Submitted  
☐ (5) Not Submitted ☐ (8) Selective Method ☐ (3) Not Applicable

Reviewers Requested:

RD  
PM  
PL  
CH  
EF

DATE SENT	DUE DATE	DATE RETURNED

RESPONSE CODE	RESPONSE DATE

|108| Status: \_\_\_\_\_

|115| FINAL Response  
ACTION Code \_\_\_\_\_

|120| Response  
\_\_\_\_\_ | \_\_\_\_\_ | \_\_\_\_\_  
MO DAY YR

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No





U.S. ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAM (TS-767)  
WASHINGTON, D.C. 20460

## APPLICATION FOR PESTICIDE:

☒ REGISTRATION  
☐ AMENDMENT

Please read instructions  
on reverse before com-  
pleting.

## SECTION I

1. COMPANY/PRODUCT NO.

2724- JUI

2. DATE

6/24/88

3. PRODUCT MANAGER

Phil Hutton (17)

4. PROPOSED CLASSIFICATION

☒ GENERAL☐ RESTRICTED

5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code)

Zoecon Corporation  
A Sandoz Company  
12200 Denton Drive  
Dallas, Texas 75234

☐ CHECK IF THIS IS A NEW ADDRESS

6. PRODUCT NAME

Zoecon RF-330 ALTOSID(R) Pellets

## SECTION II

1. SUBJECT OF AMENDMENT

☐ RESUBMISSION IN RESPONSE TO AGENCY LETTER DATED \_\_\_\_\_

☐ FINAL PRINTED LABEL IN RESPONSE TO AGENCY LETTER DATED \_\_\_\_\_

☐ OTHER (explain below)

## SECTION III

1. WILL THIS PRODUCT BE PACKAGED IN:

CHILD-RESISTANT PACKAGING ☐ YES ☒ NO

UNIT PACKAGING ☐ YES ☒ NO

If YES, unit pkg. wt. \_\_\_\_\_ No. per container \_\_\_\_\_

WATER-SOLUBLE PACKAGING ☐ YES ☒ NO

If YES, pkg. wt. \_\_\_\_\_ No. per container \_\_\_\_\_

2. TYPE OF CONTAINER

☒ METAL☒ PLASTIC☒ GLASS☐ PAPER☐ OTHER (Specify)

3. LOCATION OF NET CONTENTS

☒ LABEL ☐ CONTAINER

4. SIZE(S) OF RETAIL CONTAINER

25-100 lbs.

5. LOCATION OF LABEL DIRECTIONS

☒ ON LABEL

☐ ON MATERIAL ACCOMPANYING PRODUCT

6. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT

☒ LITHOGRAPH☐ OTHER (Specify)☒ PAPER GLUED☐ STENCILED

## SECTION IV

1. CONTACT POINT (Complete items directly below for identification of individual to be contacted,  
if necessary, to process this application).

NAME

Kelly J. Parker  
Kelly J. Parker *sw*

TITLE

Regulatory Specialist

TELEPHONE NO. (Include Area Code)

214/888-8486

2. SIGNATURE

Kelly J. Parker *sw*

3. TITLE

Regulatory Specialist

4. TYPED NAME

Kelly J. Parker

5. DATE SIGNED

6/27/88

6. DATE APPLICATION RECEIVED (Stamped)

ATTACHMENT A  
FORMULATOR'S EXEMPTION STATEMENT

EPA File Symbol or Product Registration Number: 2724-~~450~~ UU<sup>2</sup>I

Applicant's Name and Address: Zeecon Corporation, A Sandoz Company  
12200 Denton Drive, Dallas, Texas 75234

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) Our product is an end-use product, and it contains the active ingredient(s) (S)-methoprene

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) Indicate by circling the appropriate text which paragraph applies:

(A) An accurate Confidential Statement of Formula for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated \_\_\_\_\_ on file with the EPA is complete, current and accurate and contains the information requested on the current CSF form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below.

Active Ingredient

Source: Product Name and Registration No.

Applicant's authorized representative:

Kelly J. Parker  
(Signature)

Kelly J. Parker

(Typed)

Dated: 6/24/88

ATTACHMENT B

CERTIFICATION WITH RESPECT TO OFFER TO PAY AND GENERAL OFFER TO PAY

EPA File Symbol/Reg. No. 2724-~~---~~UUU Date of application 6/24/88

Name of Product Zoecon RF-330 ALTOSID Pellets

Applicant's Name and Address Zoecon Corporation, A Sandoz Company  
12200 Denton Drive, Dallas, Texas 75234

I certify that, for each study listed in the list of data requirements under Section II.A. of PR Notice 84-4 that is not entitled to exclusive use protection:

1. I have obtained the written permission of the original data submitter to cite that study in support of his application; or

2. I have notified in writing by certified mail, return receipt requested, the companies who have submitted data I have cited to support this application and have offered to: (1) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (2) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA, and the amount and terms of compensation due, if any.

The companies I have notified are: (Check one)

☒ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (Cite-All method).

☐ Those companies who have submitted the studies which I have cited (Selective method).

I hereby offer and agree to pay compensation to other parties, with regard to the approval of this application, to the extent required by section 3(c)(1)(D) and section 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

Signature: Kelley J. Parker

Title: Kelly J. Parker  
Regulatory Specialist

Date: 6/24/88



**Zoecon Corporation**

A SANDOZ Company

12005 Ford Road, Suite 800, Dallas, Texas 75234-7296, (214) 243-2321

June 24, 1988

Mr. Phil Hutton  
Product Manager (17)  
Insecticide-Rodenticide Branch  
Environmental Protection Agency  
Crystal Mall, Bldg. 2  
1921 Jefferson Davis Hwy.  
Arlington, VA 22202

RE: Zoecon RF-330 ALTOSID(R) Pellets  
Application for Pesticide Registration  
Cite-All Method

Dear Mr. Hutton:

Zoecon RF-330 ALTOSID Pellets is an extended release formulation for control of standing water and floodwater mosquitoes in small volumes of water.

Zoecon RF-330 is a design modification of the ALTOSID Briquets product, EPA Reg. No. 2724-375, to facilitate use in smaller volumes of water, e.g. cemetery vases, tree holes, etc. It is essentially identical to the ALTOSID Minikets Altotabs, EPA Reg. No. 2724-389.

The difference in the above listed products and the RF-330 is that they contain racemic methoprene; RF-330 contains (S)-methoprene.

Racemic methoprene contains two optical isomers. These isomers are designated 7(R) and 7(S). Insect enzyme systems affected by methoprene are capable of accepting only the (S) isomer. The (R) isomer is essentially an inert ingredient as it possesses no biological activity. Studies show the (S) isomer is twice as active as the racemic mixture. Therefore, only half the amount of (S)-methoprene is required in this end-use product.

(S)-methoprene is currently registered in several end-use products including ALTOSID Liquid Larvicide, EPA Reg. No. 2724-392, ALTOSID Liquid Larvicide concentrate, EPA Reg. No. 2724-393.

Tolerances already established for methoprene in conjunction with the existing exemption from the requirement of tolerances for mosquito control with methoprene in pastures, rice fields, marshlands and other non-crop areas would be applicable to this product.

Draft labeling (five copies), administrative materials and the proposed formula are enclosed. The formula for RF-330 is provided on form 8570-4. We've deleted the lines on the form for adequate spacing. The certified limits were calculated in accordance with the table of standard limits published in Federal Register 53 (86) page 15997.

Please refer to the following EPA registrations in support of the registration of Zoecon RF-330 ALTOSID Pellets:

ALTOSID Liquid Larvicide, EPA Reg. No. 2724-392

ALTOSID Liquid Larvicide Concentrate, EPA Reg. No. 2724-393

ALTOSID Briquet, EPA Reg. No. 2724-375

ALTOSID Minikets Altotabs, EPA Reg. No. 2724-389

ALTOSID CP-10, EPA Reg. No. 2724-367

KABAT Tobacco Protector, EPA Reg. No. 2724-377

(S)-Methoprene Technical, EPA Reg. No. 55947-109

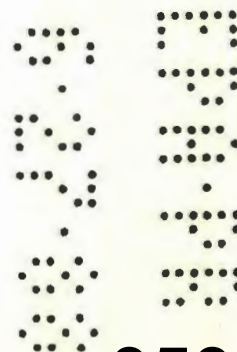
In that this application for registration is made using the cite-all method of support, a signed Certification with Respect to Offer to Pay and General Offer to Pay is included.

Best regards,

*Kelly J. Parker*

Kelly J. Parker  
Regulatory Specialist  
(800)527-0512

RF330EPA/Proj.#T87-6/lgw



**Zoecon Corporation**

*A SANDOZ Company*

12005 Ford Road, Suite 800, Dallas, Texas 75234-7296, (214) 243-2321

June 27, 1988

Mr. Phil Hutton  
Product Manager (17)  
Insecticide-Rodenticide Branch  
Registration Division (TS-767C)  
Environmental Protection Agency  
Crystal Mall, Bldg. 2  
1921 Jefferson Davis Hwy.  
Arlington, VA 22202

RE: Zoecon RF-330 ALTOSID(R) Pellets

Dear Mr. Hutton:

Please include the enclosed Application for Pesticide Registration in our file for the subject product.

The Application was inadvertently not included with the product submission package sent on June 24, 1988.

Best regards,

*Kelly G. Parker* *gkp*

Kelly G. Parker  
Regulatory Specialist  
(800)527-0512

ALTO/lgw

354





United States Environmental Protection Agency  
Office of Pesticide Programs  
Washington, DC 20460

**Data Review Record**  
Confidential Business Information - Does not contain  
National Security Information (E.O. 12065)

Pack Number

Date Received

1. Product Name

ZOECON RF - 330 ALTOSID PELLETS

Chemical Name

S-Methoprene

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
2724-UVI	242232	160		
<del>Note jacket</del>				Note jacket 2724-375 and 2724-442 are attached as references for Mike Clifford

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
	6-27-88	HUTTON/BAGLEY	17	4-2-90	5-11-90	

Instructions

Please see attached expedite memo + Mike Clifford's review enclosed. Please call me if you need more info. - I'll do what I can to help. Regards

ATTN: Mike Clifford

PAT BAGLEY PM 17 557-4412

This Section Applies to Review of Studies Only

14. Check Applicable Box				15. No. of Individual Studies Submitted		
<input type="checkbox"/>	Adverse 6(a)(2) Data (405)		<input type="checkbox"/>	Generic Data (Reregistration) (660)		
<input type="checkbox"/>	Special Review Data (870)		<input type="checkbox"/>	Product Specific Data (Reregistration) (655)		
16. Have any of the above studies (in whole or in part) been previously submitted for review?				17. Related Actions		
<input type="checkbox"/> Yes (Please identify the study(ies))				<input type="checkbox"/> No		
18.	To	Type of Review	19. Reviews Also Sent to		20. Data Review Criteria	
HED		Science Analysis & Coordination	<input type="checkbox"/>	SAC	<input type="checkbox"/>	PC
		Toxicology/HFA	<input type="checkbox"/>	TOX/HFA	<input type="checkbox"/>	PL
		Toxicology/IR	<input type="checkbox"/>	TOX/IR	<input type="checkbox"/>	EA
		Dietary Exposure	<input type="checkbox"/>	DEB	<input type="checkbox"/>	AC
		Nondietary Exposure	<input type="checkbox"/>	NDE	<input type="checkbox"/>	BA
EFED		Ecological Effects	<input type="checkbox"/>	EEB		
		Environmental Fate & Groundwater	<input type="checkbox"/>	EFGWB		
SRRD		Special Review	<input type="checkbox"/>	SR		
		Reregistration	<input type="checkbox"/>	RER		
		Generic Chemical Support	<input type="checkbox"/>	GSC		
RD		Insecticide-Rodenticide	<input type="checkbox"/>	IR		
		Fungicide-Herbicide	<input type="checkbox"/>	FH		
		Antimicrobial	<input type="checkbox"/>	AM		
		Product Chemistry	<input type="checkbox"/>			
BEAD		Precautionary Labeling				
		Economic Analysis				
		Analytical Chemistry				
		Biological Analysis				
<input type="checkbox"/> Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)				<input type="checkbox"/> Label Attached		



Please note: Attached are jackets  
2724-375 & 2724-442 to and  
review; Jacket 2724-389 has  
been cancelled due to non-payment  
of maintenance fees

Pat Bigley




 United States Environmental Protection Agency  
 Office of Pesticide Programs  
 Washington, DC 20460

## Data Review Record

 Confidential Business Information - Does not contain  
 National Security Information (E.O. 12065)

Pack Number

Date Received

## 1. Product Name

ZOECON RF - 330 ALTOSID PELLETS

## Chemical Name

S-Methoprene

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
2724-UEQ	242232	160		
				Note jacket 2724-275 and 2724-442 are attached as references for make official

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
	6-27-88	HUTTON/BAGLEY	17	4-2-90	5-11-90	

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ATTN: Mike Clifford

PAT BAGLEY, PM 17 557-4412

## This Section Applies to Review of Studies Only

14. Check Applicable Box			15. No. of Individual Studies Submitted	
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<input type="checkbox"/>	Special Review Data (870)	<input type="checkbox"/>	Product Specific Data (Reregistration) (655)	
16. Have any of the above studies (in whole or in part) been previously submitted for review?				17. Related Actions
<input type="checkbox"/> Yes (Please identify the study(ies)) <input type="checkbox"/> No				

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	<input type="checkbox"/> SAC <input type="checkbox"/> PC	A. Policy Note No. 31
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA <input type="checkbox"/> PL	
		Toxicology/IR	<input type="checkbox"/> TOX/IR	
		Dietary Exposure	<input type="checkbox"/> DEB <input type="checkbox"/> EA	
		Nondietary Exposure	<input type="checkbox"/> NDE <input type="checkbox"/> AC	
EFED		Ecological Effects	<input type="checkbox"/> EEB <input type="checkbox"/> BA	2 = data of particular concern from registration standard
		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB	
SRRD		Special Review	<input type="checkbox"/> SR	3 = data necessary to determine tiered testing requirements
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR	B. Section 18
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial	<input type="checkbox"/> AM	
		Product Chemistry		
BEAD		Precautionary Labeling		C. Inert Ingredients
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		1 = data in support of continued use of List 1 inert

☒ Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)
 ☐ Label Attached




 United States Environmental Protection Agency  
 Office of Pesticide Programs  
 Washington, DC 20460

## Data Review Record

 Confidential Business Information - Does not contain  
 National Security Information (E.O. 12065)

Pack Number

Date Received

1. Product Name

ZOECON RF - 330 ALTOSID PELLETS

Chemical Name

S-Methoprene

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
2724-UUI	242232	160		
				Note which 2724 275 and 2724-442 are attached as references for Mike Clifford

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
	6-27-88	HUTTON/BAGLEY	17	4-2-90	5-11-90	

Instructions

Please see attached expedite memo + Mike Clifford's review enclosed. Please call me if you need more info. I'll do what I can to help. Regards

ATTN: Mike Clifford

PAT BAGLEY PM 17 557 442

## This Section Applies to Review of Studies Only

14. Check Applicable Box				15. No. of Individual Studies Submitted	
<input type="checkbox"/> Adverse 6(a)(2) Data (405)		<input type="checkbox"/> Generic Data (Reregistration) (660)			
<input type="checkbox"/> Special Review Data (870)		<input type="checkbox"/> Product Specific Data (Reregistration) (655)			
16. Have any of the above studies (in whole or in part) been previously submitted for review?				17. Related Actions	
<input type="checkbox"/> Yes (Please identify the study(ies))				<input type="checkbox"/> No	
18.	To	Type of Review	19. Reviews Also Sent to		20. Data Review Criteria
HED		Science Analysis & Coordination	<input type="checkbox"/> SAC	<input type="checkbox"/> PC	A. Policy Note No. 31  <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria  <input type="checkbox"/> 2 = data of particular concern from registration standard  <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA	<input type="checkbox"/> PL	
		Toxicology/IR	<input type="checkbox"/> TOX/IR		
		Dietary Exposure	<input type="checkbox"/> DEB	<input type="checkbox"/> EA	
		Nondietary Exposure	<input type="checkbox"/> NDE	<input type="checkbox"/> AC	
EFED		Ecological Effects	<input type="checkbox"/> EEB	<input type="checkbox"/> BA	B. Section 18  <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18
		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB		
SRRD		Special Review	<input type="checkbox"/> SR		C. Inert Ingredients  <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
		Reregistration	<input type="checkbox"/> RER		
		Generic Chemical Support	<input type="checkbox"/> GSC		
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR		
		Fungicide-Herbicide	<input type="checkbox"/> FH		
		Antimicrobial	<input type="checkbox"/> AM		
		Product Chemistry			
BEAD		Precautionary Labeling			
		Economic Analysis			
		Analytical Chemistry			
		Biological Analysis			
<input type="checkbox"/> Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)			<input type="checkbox"/> Label Attached		





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Request To Expedite Review of Product Chemistry/Precautionary Label  
for EOECON RF-330 ALTOSID PELLETS

EPA Identification No. 2724-VEO

Submitted to RSB on: 4/12/90 by PM 17

DECISION MEMORANDUM

FROM: Herbert S. Harrison, Chief  
Insecticide/Rodenticide Branch

TO: Ferial Bishop, Chief  
Registration Support Branch

This is a request to expedite the review for the subject application. We have checked the applicable box(es) which identifies the reviews we wish to be done on an expedited basis.

- ☒ Product Chemistry Review  
☐ Precautionary Labeling Review

We would appreciate getting these reviews no later than 5/11/90.

An expedite is being requested for the following reason(s).

This review could not be completed by chemistry due to unavailability of 3 reference jackets. One of the jackets has been cancelled due to non-payment of maintenance fees, another jacket was involved in an EER review and the last reference jacket was going through a transfer process. The chemistry reviewer, Mike Clifford, indicated that he can do the review with 2 reference jackets. I suggested to send this through expedited process. Thanks.

ATTENTION: Mike Clifford

CONCUR: J Bishop

DO NOT CONCUR: \_\_\_\_\_

DATE: 4/12/90

Thanks!  
Pat Bagley  
PM 17  
557-4412

ZOECON CORPORATION  
12200 DENTON DRIVE OR 12005 FORD RD, #800  
DALLAS, TEXAS 75234  
TELEPHONE - (214)243-2321  
TELEFAX - (214)243-5613

MESSAGE TO:

PAT BAGLEY  
TEAM 17

FROM:

Kelly PARKER

DATE:

12 APRIL 1990

TOTAL NO. OF PAGES:  
(INCLUDING COVER)

4

IF YOU DO NOT RECEIVE ALL PAGES OR HAVE ANY PROBLEMS RECEIVING,  
PLEASE TELEPHONE (214)243-2321. THANK YOU!

FOUND LABEL & COVER LETTER  
AS SUBMITTED TO EPA IN 1983

(COPIED FROM REGISTRATION JACKET  
IN 1988)

HAPPY EASTER!



193  
Zoecon Corporation 975 California Avenue, Palo Alto, California 94304  
P.O. Box 10975, Palo Alto, California 94303

FILE

January 17, 1983

Mr. Franklin D.R. Gee (PM-17)  
Insecticide-Rodenticide Branch  
Registration Division (TS-767C)  
U.S. - Environmental Protection Agency  
Crystal Mall, Bldg. #2, Rm 207  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202

RE: Submission of Final Printed Labeling  
ALTOSID MINIKETS  
EPA Reg. No. 20954-121

Dear Mr. Gee:

Enclosed are five copies of the final printed labeling for  
ALTOSID MINIKETS.

Labeling changes required by the Agency (addition of EPA  
product reg. no. and revision of precautionary statements) have  
been included on both the container and supplemental labeling  
for this product.

Zoecon agrees to submit and/or cite all data required for  
registration/reregistration of this product under FIFRA Sec.  
3(c)(5) when the Agency requires all registrants of similar  
products to submit such data.

If you require additional information, please contact one  
directly.

Sincerely,

*Ada M. Breaux*  
Ada M. Breaux  
Registration Specialist

(01648)

Telephone (415) 857-1130 Cable: Zoecon Telex: 345550 (Zoecon PLA)

Apr 12, 90 14:41 ZOECON-DALLAS DEX-3200 243-5613

NOT REEVALUATED

In Accordance with 18 USC 82-2.  
Based on 18 USC 82-2. Dated 11-30-82

*Reference  
Label*

ALTOSID® MINIKETS

A SUSTAINED RELEASE MOSQUITO GROWTH REGULATOR TO PREVENT ADULT  
EMERGENCE IN SMALL VOLUMES OF WATER.

ACTIVE INGREDIENT:

Methoprene [Isopropyl (E,E)-11-methoxy-3,7,11-  
trimethyl 2,4-dodecadienoate]\* ..... 10.0%

INERT INGREDIENTS ..... 90.0%

TOTAL 100.0%

\*U.S. Patents 3,904,652 & 3,912,015

ALTOSID is a registered trademark of Zoecon Corporation

EPA Reg. No. 20954-121

EPA Est. No. 20954-CA-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

CONTAINS \_\_\_\_\_ MINIKETS

1.3 grams each

NOT FOR SALE OR USE AFTER \_\_\_\_\_

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION

May be harmful if absorbed through skin. Avoid contact with skin. In case of  
contact, wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

Do not apply to known fish habitat.

STORAGE AND DISPOSAL

Storage: Store in a cool place.

Disposal: Bury empty container or discard according to local regulations.

HANDLING INSTRUCTIONS

1. Do not remove ALTOSID MINIKETS from container except for immediate use.
2. Reseal container immediately to maintain MINIKET moisture control.

WARRANTY AND CONDITIONS OF SALE: Zoecon Corporation warrants that this product conforms  
to the chemical description of the label. Neither Zoecon nor the seller makes any other  
warranty, express or implied.

ZOECON CORPORATION

Palo Alto, California 94304

(09020/39C)



# DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**INTRODUCTION:** The ALTOSID MINIKET is a formulation designed to release effective levels of ALTOSID insect growth regulator over a 30-day period under typical environmental conditions. Release of ALTOSID insect growth regulator is effected by dissolution of the ALTOSID MINIKET. ALTOSID MINIKETS prevent the emergence of adult mosquitoes including *Culex* and *Culiseta* spp., as well as those of the floodwater mosquito complex (*Aedes Anopheles* and *Pooreohora* spp.) from treated water. Treated larvae continue to develop normally to the pupal stage where they die.

**APPLICATION TIME:** Placement of ALTOSID Minikets should be made at the beginning of the mosquito season. Under normal conditions repeat treatment every 30 days or as water accumulation warrants. Continue treatment through the last brood of the season. Placement may be made at any stage of larval development.

**NOTE:** This insect growth regulator has no effect on mosquitoes which have reached the pupal stage or adult stage prior to treatment.

**APPLICATION SITES:** ALTOSID MINIKETS are designed to control mosquitoes in small bodies of water which are not known fish habitat. Examples of application sites are: storm drains, catch basins, roadside ditches, ornamental ponds and fountains, seeps, pools and septic tanks, waste treatment and settling ponds, flooded crypts, transformer vaults, abandoned swimming ponds, construction and other man made depressions. For application sites connected by a water system, i.e., storm drains or catch basins, all of the water holding sites in the system should be treated to maximize the efficiency of the treatment program.

**APPLICATION RATES AND INTERVALS:** For mosquito control in non- (or low-) flow, shallow depressions (up to 2 feet in depth), treat on the basis of surface area placing 4 ALTOSID MINIKETS per 100 sq. ft.

For mosquito control in water subject to flow or deeper than 2 feet, treat on the basis of volume. Apply at the rate of 4 ALTOSID MINIKETS per 10 cu. ft. (75 gal. of water). ALTOSID MINIKETS will maintain an effective concentration throughout 4 complete volume changes per 30 day treatment interval according to the following table:

## ALTOSID MINIKETS FOR FLOWING WATER Volume /Treatment Rate/Flow

Maximum Water VOLUME in Application Site	Basic Application Rate (Altosid Minikets)	Allowable FLOW per 30 Day Mosquito Control
0-10 cu.ft. (75 gal.)	4	up to 300 gal.
10-20 cu. ft.	8	up to 600 gal.
20-30 cu. ft.	12	up to 900 gal.
30-40 cu. ft.	16	up to 1200 gal.

In the event of higher flow reduce the treatment interval proportionately using the following flow formula. Do not increase the application rate.

### FLOW ADJUSTMENT FORMULA

$$\frac{\text{Allowable Flow}^*}{\text{Actual Flow}} \times 30 = \text{Adjusted Treatment Interval (days)}$$

\* 4 Volume changes or see above table.

Example: For a 36 cu. ft. catch basin of low flow (up to 1200 gal. per 30 days) treat with 16 ALTOSID MINIKETS. For higher flow, such as 2400 gal. per 30 days the treatment interval should be reduced to 15 days ( $1200/2400 \times 30 = 15$ ).



